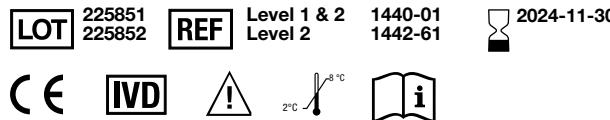


Quantimetrix® Dipper®

Urinalysis Dipstick Control Level 1 & 2



English

Intended Use

The Quantimetrix Dipper Urinalysis Dipstick Control is intended as a control for urinalysis reagent strips, microalbumin, and creatinine by the listed test methods, and as a control for confirmatory tests such as **K-CHECK** and **Ictotest®** reagent tablets, and for **hCG** methods.

Product Description

The Quantimetrix Dipper Urinalysis Dipstick Controls are supplied in two levels as 6 x 15 mL, three tubes of each level or 6 x 15 mL Level 1 only. They are liquid, ready-to-use, requiring no reconstitution or dilution. They are prepared from human urine fortified to target levels with compounds that produce the desired reaction when tested by the methods indicated in the **Intended Use** section. Preservatives have been added to inhibit microbial growth.

Caution

Contains human urine, human blood cells and human Chorionic Gonadotropin (hCG) from pregnancy urine. The human hCG source material and all blood donor units comprising the human cell source material used in the manufacture of this product have been tested and found nonreactive for Hepatitis B Surface Antigen and Hepatitis C and HIV 1 & 2 antibody when tested by FDA accepted methods. No known test method can assure that a product derived from human material does not contain Hepatitis or HIV virus. Handle the QC material as you would a patient sample. QC materials should be used and disposed of in accordance with regulatory and accreditation requirements.

Warning ! Hazard (H) and Precautionary (P) Statements

Contains Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, Level 1; 2,4-Pentanedione, Level 2.

H317 – May cause an allergic skin reaction.

P261 – Avoid breathing vapors, mist, or spray.

P272 – Contaminated work clothing should not be allowed out of the workplace.

P280 – Wear protective gloves, protective clothing, and eye protection.

P302+P352 – IF ON SKIN: Wash with plenty of water.

P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 – Take off contaminated clothing and wash it before reuse.

P501 – Dispose of contents/container in accordance with local, regional, national, and international regulations.

Safety Data Sheet (SDS) available for professional users at quantimetrix.com.

Storage and Stability

The Urinalysis Dipstick Control Kit should be stored at 2°C–8°C when not in use. **Do not freeze**. When stored at 2°C–8°C, the controls are stable until the expiration date stated on the label. After initial use, each tube of control is stable for 3 months or 20 dipstick immersions, whichever occurs first. Discard the controls if turbid or any evidence of microbial contamination is present. Discard controls in the same manner as other biological specimens, according to local guidelines. The Level 1 and 2 Controls are suitable for use as negative and positive controls for hCG methods until the expiration date.

Procedure for Dipstick Testing

Remove the controls from the refrigerator and allow to come to room temperature (18°C–25°C), at least 15 minutes, depending on remaining volume. Mix gently by inversion to assure homogeneity of the contents. Avoid foaming. Remove cap and immerse the dipstick in the control tube as if it were a patient sample. Read the urine dipsticks, visually or with an instrumental reader, in accordance with the manufacturers' instructions. Immediately recap the controls and return them to 2°C–8°C when not in use.

Caution

Once control fluid is removed for hCG or confirmatory testing that control tube must not be used for dipstick immersion testing. Once a control tube is used for dipstick immersion testing it must not be used for hCG or confirmatory testing.

Procedure for hCG Testing

Note: The bottles of Level 1 Control are to be used as a negative control for hCG methods. The bottles of Level 2 Control are to be used as a positive control for hCG methods. Remove the controls from the refrigerator and allow to come to room temperature (18°C–25°C), at least 15 minutes, depending on remaining volume. Use the hCG positive and negative controls as if they were patient specimens in accordance with the hCG test kit manufacturer's instructions. Immediately recap the controls and return them to 2°C–8°C when not in use.

Expected Values

For **visual readings**, the expected ranges have been established from interlaboratory data by comparing the dipstick reaction that occurs with the controls to the color comparison chart with multiple lots of each manufacturers' dipsticks or reagent tablets. For expected values for urinalysis reagent strips not listed, please contact Quantimetrix Technical Services. For **instrument readings**, the expected ranges have been established from interlaboratory data from multiple lots of each manufacturers' dipsticks. Each laboratory should establish its own precision parameters. For **specific gravity**, the expected ranges by refractometer have been established from interlaboratory data. For **hCG**, the positive and negative results were obtained by testing each lot number of the controls with multiple lot numbers of different hCG test kits with sensitivities of $\geq 25 \text{ mIU/mL}$.

Limitations

Any future changes made by the manufacturer of a test method may give different values from the indicated range. Detailed information on the limitations of each test method is included in the limitations section of the manufacturers' package insert. Technical updates can be found on our website. The Quality Control Log can be downloaded from the Quantimetrix website at quantimetrix.com or contact Tech Support at (310) 536-0006, option 3.

Repeated immersions of some urinalysis dipsticks in the Level 2 control may result in a diminished blood result. If a negative result for blood is obtained in Level 2 before the 20 dip or 3 month open vial period, a new control should be used.

Endogenous crystalline sediment may be present and does not affect the performance of the product.

Chemstrip/Combur/Multistix/Urocheck Users

Colors produced by the **urobilinogen** and/or **bilirubin** reactions on these dipsticks with the urinalysis dipstick control may not be characteristic of those shown on the manufacturer's label when reading the dipstick reactions visually. The urobilinogen reactions are consistent and intensify with the increase in the urobilinogen concentration but may not provide an exact color match to those displayed on the label.

Note: Siemens® CLINITEK 50 and Siemens® STATUS or CLINITEK STATUS PLUS may see an Albumin/Creatinine ratio result of "Abnormal" with the Level 1 control.

Deutsch

Verwendungszweck

Die Quantimetrix Dipper Urinalysis Dipstick Control ist als Kontrolle für Urinalyse-Reagenzstreifen, Mikroalbumin und Kreatinin gemäß den aufgeführten Testmethoden sowie als Kontrolle für Bestätigungstests wie z. B. **K-CHECK** und **Ictotest®** Reagenz-Tabletten und für **hCG**-Methoden bestimmt.

Produktbeschreibung

Die Quantimetrix Dipper Urinalysis Dipstick Controls werden in Packungen von 6 x 15 ml (jeweils drei Tuben der beiden Stufen) bzw. von 6 x 15 ml (nur Stufe 2) geliefert. Es handelt sich um gebrauchsfertige Flüssigkontrollen, die nicht rekonstituiert oder verdünnt werden müssen. Sie werden aus Humanurin hergestellt, der mit Verbindungen, die bei Durchführung der im Abschnitt **Verwendungszweck** angegebenen Testmethoden die gewünschte Reaktion erzeugen, auf die Sollwerte angereichert wurde. Zur Hemmung mikrobiellen Wachstums wurden Konservierungsstoffe hinzugefügt.

Warnhinweis

Enthält menschlichen Urin, menschliche Blutkörperchen und menschliches Choriongonadotropin (hCG) aus Urin bei Schwangerschaft. Das menschliche hCG-Quellenmaterial und alle bei der Produktherstellung verwendeten Blutspenden, die das menschliche Zellenquellenmaterial beinhalten, wurden unter Einhaltung anerkannter FDA-Methoden auf Hepatitis B-Oberflächenantigene, Hepatitis C und Antikörper gegen HIV 1 & 2 getestet. Die Testergebnisse waren nicht-reaktiv. Es sind keine Testmethoden bekannt, mit denen garantiert werden kann, dass die aus menschlichem Material gewonnenen Produkte frei von Hepatitis- oder HIV-Viren sind. Die Materialien für die Qualitätskontrolle sollten wie Patientenproben gehandhabt werden. Die Materialien müssen im Einklang mit den gesetzlichen Bestimmungen und Zulassungsvorschriften verwendet und entsorgt werden.

Achtung ! Gefahrenhinweise (H) Sicherheitshinweise (P)

Gemisch, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, Stufe 1; 2,4-Pentanedione, Stufe 2.

H317 – Kann allergische Hautreaktionen verursachen.

P261 – Einatmen von Nebel, Dämpfen, Aerosol vermeiden.

P272 – Kontaminierte Arbeitskleidung nicht außerhalb des Arbeitsplatzes tragen.

P280 – Schutzhandschuhe, Schutzkleidung und Augenschutz tragen.

P302+P352 – BEI KONTAKT MIT DER HAUT: Mit viel Wasser waschen.

P333+P313 – Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/Ärztliche Hilfe hinzuziehen.

P362+P364 – Alle kontaminierten Kleidungsstücke sofort ausziehen und vor erneutem Tragen waschen.

P501 – Inhalt/Behälter entsprechend örtlichen, regionalen, nationalen und internationalen Richtlinien der Entsorgung zu führen.

Sicherheitsdatenblatt (SDB) steht Ihnen im Internet unter quantimetrix.com zur Verfügung.

Lagerung und Stabilität

Das Urinalysestäbchen-Kontroll-Kit sollte bei Nichtgebrauch bei 2°C–8°C gelagert werden. **Nicht einfrieren**. Bei Lagerung bei 2°C–8°C sind die Kontrollen bis zum auf dem Etikett angegebenen Verfallsdatum stabil. Nach dem ersten Gebrauch ist jede Tube mit der Kontrolle 3 Monate lang bzw. für 20 Eintauchungen des Teststäbchens stabil, je nachdem was zuerst eintritt. Falls die Kontrollen trüb werden oder Hinweise auf eine mikrobielle Verunreinigung vorliegen, müssen sie entsorgt werden. Kontrollen auf gleiche Weise wie andere biologische Proben gemäß den örtlichen Richtlinien entsorgen. Die Stufe-1- und Stufe-2-Kontrollen sind bis zum Verfallsdatum als negative und positive Kontrollen für hCG-Methoden geeignet.

Verfahren für TeststäbchenTests

Die Kontrollen aus dem Kühlschrank nehmen und, je nach verbliebenem Volumen, mindestens 15 Minuten lang auf Raumtemperatur (18°C–25°C) erwärmen lassen. Durch Umdrehen vorsichtig mischen, damit der Inhalt homogen wird. Nicht schütteln lassen. Den Verschluss abnehmen und das Teststäbchen wie eine Patientenprobe in die Kontrolltröhre einführen. Die Urinteststäbchen visuell oder in einem Lesegerät gemäß den Herstelleranweisungen ablesen. Die Kontrollen bei Nichtgebrauch sofort wieder verschließen und bei 2°C–8°C aufbewahren.

Achtung

Wenn die Kontrollflüssigkeit für hCG- oder Bestätigungstests entfernt wird, darf dieses Kontroll-Triströhren nicht für Teststäbchen-Eintauchtests verwendet werden. Wenn ein Kontroll-Triströhren für Teststäbchen-Eintauchtests verwendet wird, darf es nicht für hCG- oder Bestätigungstests verwendet werden.

Verfahren für hVG-Tests

Hinweis: Die Fläschchen mit der Level-1-Kontrolle sind bei hCG-Methoden als negative Kontrolle vorgesehen. Die Fläschchen mit der Level 2 Kontrolle sind bei hCG-Methoden als positive Kontrolle vorgesehen. Die Kontrollen aus dem Kühlschrank nehmen und, je nach verbliebenem Volumen, mindestens 15 Minuten lang auf Raumtemperatur (18°C–25°C) erwärmen lassen. Die hCG-positiven und -negativen Kontrollen nach Anweisungen des Herstellers des hCG-Test-Kits wie Patientenproben benutzen. Die Kontrollen bei Nichtgebrauch sofort wieder verschließen und bei 2°C–8°C aufbewahren.

Erwartete Werte

Für **visuelle Messungen** wurden die erwarteten Bereiche aus den Daten verschiedener Labors bestimmt, indem die mit den Kontrollen erhaltene Teststäbchenreaktion mit der Farbvergleichstabelle verglichen wurde, die Farben für mehrere Chargen der Teststäbchen bzw. Reagenztabletten jedes Herstellers enthält. Erwartete Werte für nicht aufgeführte Urinalyse-Reagenzstreifen sind von Quantimetrix Technical Services erhältlich.

Für **Gerätemessungen** wurden die erwarteten Werte anhand von Daten verschiedener Labors und mehreren Chargen von Teststäbchen jedes Herstellers bestimmt. Jedes Labor sollte seine eigenen Präzisionsparameter bestimmen. Für die **relative Dichte** wurden die mit dem Refraktometer ermittelten, erwarteten Bereiche aus Daten von verschiedenen Labors bestimmt. Für **hCG** wurden die positiven und negativen Ergebnisse durch Testen jeder Chargennummer der Kontrollen mit mehreren Chargennummern verschiedener hCG-Test-Kits mit Sensitivitäten von $\geq 25 \text{ mE/mL}$ erzielt.

Einschränkungen

Falls der Hersteller einer Testmethode zu einem späteren Zeitpunkt Änderungen vornimmt sollte, kann dies zu Werten führen, die vom angegebenen Bereich abweichen. Ausführliche Informationen über die Einschränkungen der einzelnen Testmethoden sind dem Abschnitt „Einschränkungen“ der Packungsbeilagen der jeweiligen Hersteller zu entnehmen. Technische Updates sind auf unserer Website erhältlich. Sie erhalten das Qualitätskontrollprotokoll durch Herunterladen über die Website von Quantimetrix unter quantimetrix.com, oder indem Sie sich an den technischen Support unter der Rufnummer +1 (310) 536-0006, Option 2 wenden.

Wiederholtes Eintauchen einiger Urinalyse-Teststreifen in die Level-2-Kontrolle könnte zu einem herabgesetzten Blutergebnis führen. Ergibt Level 2 vor dem 20. Eintauchen oder dem 3-Monate-Zeitraum für Endogenes Kristallines Sediment kann vorhanden sein und beeinträchtigt die Leistung des Produkts nicht.

Chemstrip/Combur/Multistix/Urocheck-Benutzer

Farben, die durch das **Urobilinogen** erzeugt werden, und/oder **Bilirubinreaktionen** auf diesen Teststäbchen mit der Urinalysestäbchen-Kontrolle sind möglicherweise nicht charakteristisch für die auf dem Etikett des Herstellers aufgeführten Werte, wenn die Teststäbchen-Reaktionen visuell abgelesen werden. Die Urobilinogen-Reaktionen sind konsistent und nehmen bei Zunahme der Urobilinogenkonzentration an Intensität zu, stimmen farblich jedoch möglicherweise nicht exakt mit den auf dem Etikett angegebenen Farben überein.

Hinweis: Siemens® CLINITEK 50 und Siemens® STATUS oder CLINITEK STATUS PLUS können bei der Stufe-1-Kontrolle unter Umständen ein „anormales“ Albumin/Kreatinin-Verhältnis anzeigen.

Français

Utilisation prévue

Le Quantimetrix Dipper Urinalysis Dipstick Control a pour fonction de vérifier les bandes de réactif d'analyse d'urine et le dosage de la micro-albumine et de la créatinine selon les méthodes de test indiquées et, de contrôler les tests de confirmation tels ceux des tablettes de réactif **K-CHECK** et **Ictotest®** ainsi que les méthodes **hCG**.

Description du produit

Les Quantimetrix Dipper Urinalysis Dipstick Controls existent en deux niveaux, conditionnés en 6 tubes de 15 ml (trois tubes de chaque niveau ou six tubes de niveau 2 uniquement). Ils se présentent sous la forme d'un liquide prêt à l'emploi ne nécessitant ni reconstitution, ni dilution. L'urine humaine entre dans leur composition et, pour atteindre les niveaux cibles, ils sont enrichis de composés produisant la réaction souhaitée lorsqu'ils sont testés selon les méthodes indiquées dans la section **Utilisation prévue**. Des conservateurs ont été ajoutés pour inhiber la prolifération microbienne.

Mise en garde

Contient de l'urine humaine, des cellules sanguines humaines et de l'hormone chorionique gonadotrope humaine (hCG) provenant d'urine de femmes enceintes. Les matériaux humains de la source d'hCG ainsi que toutes les unités de donneurs de sang composant les matériaux sanguins humains utilisés pour la fabrication de ce produit ont fait l'objet de tests conformes aux méthodes approuvées par la FDA. Ils se sont révélés non réactifs à l'antigène de surface de l'hépatite B, ainsi qu'à l'anticorps de l'hépatite C et du VIH 1 et 2. Aucune méthode de test connue n'est en mesure de garantir qu'un produit dérivé de matériel humain ne contient pas le virus de l'hépatite ou du VIH. Manipuler les matériaux du contrôle de qualité de la même façon que pour un échantillon de patient. Ces matériaux doivent être utilisés et éliminés conformément aux exigences réglementaires et critères d'accréditation.

Attention ! Mentions de danger (H) Conseils de prudence (P)

Contains Mélange, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, niveau 1; 2,4-Pentanedione, niveau 2.

H317 – Peut causer une réaction allergique cutanée.

P261 – Éviter de respirer les vapeurs, les brouillards ou les aérosols.

P272 – Les vêtements de travail contaminés ne doivent pas quitter le lieu de travail.

P280 – Porter des gants de protection, des vêtements de protection et un dispositif de protection des yeux.

P302+P352 – EN CAS DE CONTACT AVEC LA PEAU : laver à grande eau.

P333+P313 – En cas d'irritation ou d'éruption cutanée : consulter un médecin.

P362+P364 – Enlever les vêtements contaminés et les laver avant réutilisation.

P501 – Éliminer le contenu/contenant conformément aux réglementations locales, régionales, nationales et internationales.

Une fiche de sécurité (SDS) est à disposition des utilisateurs professionnels sur le site quantimetrix.com.

Stockage et stabilité

Le kit de contrôle de bâtonnet d'analyse d'urine doit être entreposé entre 2°C et 8°C entre deux utilisations. **Ne pas congeler.** Stockés à la température indiquée, les contrôles sont stables jusqu'à la date de péremption figurant sur l'étiquette. Après la première utilisation, chaque tube de contrôle reste stable pendant 3 mois ou 20 immersions de bâtonnets, selon la première échéance. Toute solution de contrôle présentant des traces de turbidité ou de contamination microbienne doit être jetée. Jetez les contrôles en procédant comme pour d'autres spécimens biologiques, conformément aux directives locales en vigueur. Les contrôles de niveau 1 et 2 sont prévus pour être utilisés comme contrôles négatif et positif avec les méthodes hCG jusqu'à la date de péremption.

Procédure de test de bâtonnet

Sortez les contrôles du réfrigérateur et attendez qu'ils soient à température ambiante (18°C à 25°C); patientez pendant au moins 15 minutes, en fonction du volume restant. Retournez doucement le flacon pour en mélanger le contenu jusqu'à ce qu'il soit homogène. Évitez de faire mousser. Retirez le bouchon et trempez le bâtonnet dans le tube de contrôle comme s'il s'agissait d'un échantillon prélevé sur un patient. Interprétez les bâtonnets d'analyse d'urine, visuellement ou à l'aide d'un lecteur prévu à cet effet, conformément aux instructions du fabricant. Rebouchez immédiatement les contrôles et entreposez-les entre 2°C et 8°C entre deux utilisations.

Attention

Une fois que le liquide de contrôle est retiré pour le test hCG ou les tests de confirmation, ce tube de contrôle ne doit pas être utilisé pour les tests d'immersion du bâtonnet. Une fois qu'un tube de contrôle a été utilisé pour des tests d'immersion du bâtonnet, il ne doit pas être réutilisé pour les tests hCG ou de confirmation.

Procédure de test HCG

Remarque: Les flacons de contrôle niveau 1 peuvent servir de contrôle négatif pour les méthodes HCG. Les flacons de contrôle niveau 2 peuvent servir de contrôle positif pour les méthodes HCG. Sortez les contrôles du réfrigérateur et attendez qu'ils soient à température ambiante (18°C à 25°C); patientez pendant au moins 15 minutes, en fonction du volume restant. Traitez les contrôles positif et négatif HCG comme s'il s'agissait d'échantillons prélevés sur des patients conformément aux instructions du fabricant du kit de test HCG. Rebouchez immédiatement les contrôles et entreposez-les entre 2°C et 8°C entre deux utilisations.

Valeurs attendues

Pour les **lectures visuelles**, les fourchettes de valeurs attendues ont été établies à partir de données émanant de plusieurs laboratoires en comparant la réaction du bâtonnet aux contrôles à la charte colorimétrique illustrant les lots de bâtonnets et de tablettes de réactif de chaque fabricant. Pour les valeurs attendues dans le cas des bandes de réactif d'analyse d'urine non listées, contactez les services techniques de Quantimetrix. Pour les **lectures instrumentales**, les fourchettes de valeurs attendues ont été établies à partir de données émanant de plusieurs laboratoires portant sur plusieurs lots de bâtonnets de chaque fabricant. Il incombe à chacun de ces laboratoires de déterminer ses propres paramètres de précision. Pour la **densité spécifique**, les fourchettes de valeurs attendues par refractométrie ont été établies à partir de données émanant de plusieurs laboratoires. Pour l'**HCG**, les résultats positif et négatif ont été obtenus en testant des lots de contrôles de tous types avec des lots de kits de test HCG de divers types ayant des sensibilités $\geq 25 \text{ mIU/mL}$.

Limitations

Toute modification ultérieure par le fabricant d'une méthode de test est susceptible d'entrainer des résultats divergents de la plage indiquée. Le détail des limitations inhérentes à chaque méthode de test est décrit dans la section Limitations de la notice fournie par le fabricant. Les mises à jour techniques sont disponibles sur notre site Web. Vous pouvez télécharger le journal de contrôle de la qualité sur le site Web de Quantimetrix (quantimetrix.com) ou contacter l'assistance technique au +1 (310) 536-0006, option 3.

Les trempages répétés de certaines bandelettes de contrôle urinaire dans le contrôle de niveau 2 peuvent diminuer la concentration de sang détectée. Si un résultat négatif est obtenu pour la détection de sang dans le niveau 2 avant 20 trempages ou pendant la période de 3 mois qui suit l'ouverture du flacon, il faut utiliser un nouveau contrôle.

Des sédiments cristallins endogènes peuvent être présents, mais ils n'affectent pas la performance du produit.

Utilisateurs de bandes Chemstrip/Combur/Multistix/Urocheck

Les colorations développées par les réactions de l'**urobilinochrome** et/ou de la **bilirubine** sur ces bâtonnets avec le contrôle de bâtonnet d'analyse d'urine ne sont pas forcément caractéristiques de celles illustrées sur l'étiquette du fabricant lorsque les réactions des bâtonnets sont interprétées visuellement. Les réactions à l'urobilinochrome sont homogènes et s'intensifient si la concentration en urobilinochrome augmente, mais il se peut que la couleur ne soit pas exactement celle indiquée sur l'étiquette.

Remarque: les analyseurs CLINITEK 50 Siemens® et STATUS ou CLINITEK STATUS PLUS Siemens® peuvent indiquer un rapport albumine/creatinine « abnormal » avec le témoin de niveau 1.

Italiano

Finalità d'uso

Il Quantimetrix Dipper Urinalysis Dipstick Control è pensato per essere impiegato come un controllo per strisce reattive per l'analisi delle urine, come un controllo per la microalbumina e la creatinina ottenute dai metodi di analisi elencati, e come un controllo per test di conferma a reagenti in compresse quali **K-CHECK e Ictotest**, e per metodo **HCG**.

Descrizione del prodotto

I Quantimetrix Dipper Urinalysis Dipstick Controls vengono forniti in due livelli: 6 x 15 ml, tre provette per ogni livello, oppure 6 x 15 ml solo livello 2. Sono liquidi, pronti per l'uso e non richiedono ricostituzione né diluizione. Vengono preparati a partire da urina umana, fortificata per raggiungere livelli target con composti che producono la reazione desiderata se sottoposti a test mediante i metodi indicati nella sezione **Finalità d'uso**. Sono stati aggiunti dei conservanti per inibire la crescita microbica.

Attenzione

Contiene urina umana, cellule sanguigne umane e gonadotropina corionica umana (hCG) derivante da urina di donne gravide. Il materiale di origine della hCG umana e tutte le unità di sangue di donatore che compongono il materiale di origine a base di cellule umane utilizzato per preparare questo prodotto sono stati testati e trovati non reattivi per l'antigene di superficie dell'hépatite B e gli anticorpi contro l'hépatite C e l'HIV 1 e 2 quando analizzati con metodi approvati dalla FDA. Non si conoscono metodi di analisi che possano assicurare che un prodotto derivato da materiale umano non contenga i virus dell'hépatite o dell'HIV. Trattare il materiale per CO come si tratterebbero i campioni di pazienti, i materiali di CQ vanno usati e smaltiti attenendosi ai requisiti normativi e di accreditazione.

Attenzione ! Indicazioni di pericolo (H) Indicazioni precauzionali (P)

Miscela, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, livello 1; 2,4-Pentanedione, livello 2.

H317 – Può provocare una reazione allergica cutanea.

P261 – Evitare di respirare i vapori, la nebbia o le particelle nebulizzate.

P272 – Gli indumenti di lavoro contaminati non devono essere portati fuori dal luogo di lavoro.

P280 – Indossare guanti protettivi, indumenti protettivi e protezioni per gli occhi.

P302+P352 – IN CASO DI CONTATTO CON LA PELLE: lavare abbondantemente con acqua.

P333+P313 – In caso di irritazione o eruzione della pelle: consultare/chiamare un medico.

P362+P364 – Togliere gli indumenti contaminati e lavarli prima del riutilizzo.

P501 – Smaltire i contenuti/contenitori in conformità alle normative locali, regionali, nazionali e internazionali. Scheda informativa sulla sicurezza (SDS) ad uso professionale disponibile al sito quantimetrix.com.

Conservazione e stabilità

Il kit di controllo per l'esame delle urine tramite dipstick dovrebbe essere conservato a una temperatura di 2°C–8°C quando non viene impiegato. Non congelare. Se conservati a 2°C–8°C i controlli sono stabili fino alla data di scadenza indicata sull'etichetta. Dopo il primo utilizzo ogni provetta di controllo è stabile per 3 mesi o per 20 immersioni di dipstick, a seconda di quale dei due eventi si verifichi per primo. Eliminare i controlli se torbidi o se vi sono segni di contaminazione batterica. Eliminare i controlli allo stesso modo degli altri campioni biologici secondo le linee guida locali. I controlli di Livello 1 e 2 sono idonei all'uso come controlli negativo e positivo per i metodi hCG fino alla data di scadenza.

Procedura per eseguire il test del dipstick

Prelevare i controlli dal frigorifero e far raggiungere la temperatura ambiente (18°C–25°C) attendendo almeno 15 minuti, in base al volume restante. Per garantire l'omogeneità del contenuto, miscelare delicatamente mediante capovolgimento. Prevenire la formazione di schiuma. Rimuovere il tappo e immergere il dipstick nella provetta del controllo, come se si trattasse di un campione di un paziente. Leggere il dipstick dell'urina, a occhio nudo o mediante apposita strumentazione di lettura, in conformità alle istruzioni fornite dal produttore. Ritappare immediatamente i controlli e riportarli alla temperatura di 2°C–8°C subito dopo l'uso.

Attenzione

Una volta che il liquido di controllo venga rimosso per test hCG o di conferma, quella provetta di controllo non deve essere usata per l'analisi mediante immersione di dipstick. Una volta che la provetta di controllo venga usata per l'analisi mediante immersione di dipstick, non deve essere usata per i test hCG o di conferma.

Procedura per eseguire il test dell'hCG

Nota: I flaconi del Controllo di Livello 1 devono essere impiegati come controllo negativo per metodi di misurazione delle hCG. I flaconi del Controllo di Livello 2 devono essere impiegati come controllo positivo per metodi di misurazione delle hCG. Prelevare i controlli dal frigorifero e far raggiungere la temperatura ambiente (18°C–25°C) attendendo almeno 15 minuti, in base al volume restante. Impiegare i controlli positivi e negativi per le hCG, come se si trattasse di campioni di pazienti, conformemente alle istruzioni fornite dal produttore del kit di analisi delle hCG. Ritappare immediatamente i controlli e riportarli alla temperatura di 2°C–8°C subito dopo l'uso.

Valori attesi

Per **lettura a occhio** nudo i range di valori attesi sono stati stabiliti sulla base di dati interni di laboratorio ottenuti confrontando la reazione del dipstick che si verifica con i controlli con la tabella di confronto dei colori per diversi loti di dipstick o reagenti in compresse di ogni produttore. Per i valori attesi per le strisce reagenti per analisi delle urine non presenti nell'elenco si prega di contattare l'Assistenza Tecnica Quantimetrix. Per **lettura supportate da strumentazione** i range di valori attesi sono stati stabiliti sulla base di dati interni di laboratorio ottenuti da più lotti di dipstick di ogni produttore. È opportuno che ogni laboratorio determini i propri parametri di precisione. Per il **peso specifico** i range di valori attesi ottenuti mediante rifrattometro sono stati stabiliti sulla base di dati interni di laboratorio. Per le **hCG** i risultati positivi e negativi sono stati ottenuti sottoponendo a test ogni numero di lotto dei controlli con più numeri di lotto di diversi kit di analisi delle hCG aventi una sensibilità di $\geq 25 \text{ mIU/mL}$.

Limitsi

Eventuali future modifiche apportate dal produttore di un metodo di analisi possono originare valori diversi dal range indicato. Nella sezione **Limitsi** delle istruzioni fornite dal produttore sono contenute informazioni dettagliate sui limiti di ogni metodo di analisi sono contenute. Aggiornamenti tecnici sono ottenibili dal nostro sito web. Il registro del controllo della qualità si può ottenere scaricandolo dal sito web Quantimetrix all'indirizzo quantimetrix.com oppure contattando il team del Supporto tecnico al numero +1 (310) 536-0006, opzione 3. Immersioni ripetute di alcune strisce reattive per analisi delle urine nel controllo di Livello 2 potrebbe determinare risultati inferiori dei valori ematici. Se si ottiene un risultato negativo per i valori ematici nel Livello 2 prima di 20 immersioni o di un periodo di apertura del flacone di 3 mesi, va usato un nuovo controllo.

Possono essere presenti sedimenti cristallini endogeni; tali sedimenti non influiscono sulle prestazioni del prodotto.

Utilizzatori di Chemstrip/Combur/Multistix/Urocheck

I colori prodotti dalle reazioni di **urobilinogeno** e/o **bilirubina** su questi dipstick con il Controllo dipstick urina potrebbero non rispecchiare quelli illustrati sull'etichetta del fabbricante quando le reazioni del dipstick vengono lette visivamente. Le reazioni dell'urobilinogeno sono costanti e aumentano di intensità all'aumentare della concentrazione di urobilinogeno ma è possibile che non vi sia un'esatta corrispondenza di colore con quelle mostrate sull'etichetta.

Nota: Siemens® CLINITEK 50 e Siemens® STATUS o CLINITEK STATUS PLUS potrebbero riscontrare risultati "Anomaly" per il rapporto albumina/creatinina con il controllo di Livello 1.

Español

Uso previsto

El Quantimetrix Dipper Urinalysis Dipstick Control se utiliza como control para las tiras reactivas de análisis de orina, microalbúmina y creatinina con los métodos indicados, y como control de pruebas de confirmación, como las tabletas reactivas K-CHECK e Ictotest, y para los métodos de detección de hCG.

Descripción del producto

Los Quantimetrix Dipper Urinalysis Dipstick Controls se suministran en dos concentraciones con 6 x 15 ml, tres tubos de cada concentración, o 6 x 15 ml de la concentración 2 solamente. Son líquidos listos para su uso que no necesitan reconstitución ni dilución. Se preparan a partir de orina humana reforzada hasta las concentraciones buscadas con compuestos que producen la reacción deseada cuando se estudian con los métodos indicados en la sección **Uso previsto**. Se han añadido conservantes para inhibir la proliferación microbiana.

Precaución

Contiene orina humana, células sanguíneas humanas y gonadotropina coriónica humana (hCG) de la orina del embarazo. El material fuente del hCG humano y de todas las unidades donantes de sangre que comprenden el material fuente de células humanas utilizado en la fabricación de este producto se ha probado y no se ha detectado ningún reactivo para el antígeno de superficie de la Hepatitis B ni anticuerpos de Hepatitis C y VIH 1 y 2 cuando las pruebas se realizan con métodos aceptados por la FDA. Ningún método de prueba conocido puede asegurar que un producto derivado de material humano no contenga hepatitis o virus VIH. Trabaje con el material QC como lo haría con una muestra de paciente. Los materiales QC deben usarse y eliminarse de acuerdo con los requisitos reglamentarios y de acreditación.

Atención ! Indicaciones de peligro (H) Consejos de precaución (P)

Mezcla, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, nivel 1; 2,4-Pentanedione, nivel 2.
 H317 - Puede causar una reacción alérgica cutánea.
 P261 - Evite respirar vapores, niebla o aerosol.
 P272 - La ropa de trabajo contaminada no debe sacarse del lugar de trabajo.
 P280 - Lleve guantes, prendas y gafas de protección.
 P302+P352 - EN CASO DE CONTACTO CON LA PIEL: lave con agua abundante.
 P333+P313 - Si aparece irritación o erupción cutánea: consulte a un médico.
 P362+P364 - Quitese la ropa contaminada y lávela antes de volver a utilizarla.
 P501 - Elimine el contenido/contenedor conforme a la normativa local, regional, nacional e internacional vigente.
 La ficha de datos de seguridad (SDS) está disponible para los usuarios profesionales en quantimetrix.com.

Almacenamiento y estabilidad

El control de la tira reactiva para análisis de orina se debe almacenar a 2°C–8°C cuando no se utilice. **No congelar.** Cuando se almacenan a 2°C–8°C, los controles permanecen estables hasta la fecha de caducidad que figura en la etiqueta. Después del primer uso, cada tubo de control permanece estable durante 3 meses o 20 inmersiones de la tira reactiva, lo que suceda primero. Deseche el control si tiene un aspecto turbio o si presenta signos de contaminación microbiana. Desechar los controles de la misma forma que cualquier otra muestra biológica, conforme a las normativas locales. Los controles de nivel 1 y 2 son aptos para usarse como control negativo y positivo para métodos de detección de hCG hasta la fecha de vencimiento.

Procedimiento de estudio con tira reactiva

Extraiga los controles del refrigerador y déjelos estabilizar a temperatura ambiente (18°C–25°C) durante al menos 15 minutos, dependiendo del volumen que quede en el vial. Invierta suavemente el control para garantizar la homogeneidad del contenido. Evite la formación de espuma. Quite el tapón y sumerja la tira reactiva en el tubo de control como si fuera una muestra de paciente. Lea las tiras reactivas de orina, visualmente o con un lector instrumental, de acuerdo con las instrucciones del fabricante. Tape inmediatamente los controles y vuelva a almacenarlos a 2°C–8°C cuando no los utilice.

Advertencia

Una vez que el líquido de control es eliminado para detección de gonadotropina coriónica humana (hCG) o pruebas de confirmación, ese tubo de control no debe usarse para realizar pruebas de inmersión de la tira reactiva. Una vez que un tubo de control se usa para realizar una prueba de inmersión de la tira reactiva, no deberá usarse para detectar hCG o pruebas de confirmación.

Procedimiento de estudio de hCG

Nota: Los frascos de control de concentración 1 se deben usar como control negativo de los métodos de hCG. Los frascos de control de concentración 2 se deben usar como control positivo de los métodos de hCG. Extraiga los controles del refrigerador y déjelos estabilizar a temperatura ambiente (18°C–25°C) durante al menos 15 minutos, dependiendo del volumen que quede en el vial. Use los controles positivo y negativo de hCG como si fueran muestras de paciente, de acuerdo con las instrucciones del fabricante del juego de análisis de hCG. Tape inmediatamente los controles y vuelva a almacenarlos a 2°C–8°C cuando no los utilice.

Expectativa de resultados

En el caso de **lecturas visuales**, los intervalos esperados se han establecido a partir de datos de varios laboratorios, comparando la reacción de la tira reactiva que se produce con los controles, con la carta de comparación de colores de varios lotes de tiras reactivas o tabletas de reactivo de cada fabricante. En cuanto a los valores esperados de las tiras de reactivo para análisis de orina que no figuren, póngase en contacto con el Servicio Técnico de Quantimetrix. En el caso de **lecturas con instrumento**, los intervalos esperados se han establecido a partir de datos obtenidos en varios laboratorios con múltiples lotes de tiras reactivas de cada fabricante. Cada laboratorio deberá establecer sus propios parámetros de precisión. En el caso de la **densidad específica**, los intervalos esperados con el refractómetro se han establecido a partir de datos obtenidos en varios laboratorios. En el caso de **hCG**, los resultados positivo y negativo se obtuvieron estudiando cada número de lote de los controles con múltiples números de lote de diferentes juegos de análisis de hCG con sensibilidades de $\geq 25 \text{ mIU/mL}$.

Limitaciones

Cualquier cambio futuro que haga el fabricante del método de estudio puede originar valores diferentes al intervalo indicado. En la sección Limitaciones del folleto de los fabricantes se incluye una información detallada de las limitaciones de cada método de análisis. Encuentre la información técnica actualizada en nuestro sitio web. El registro de control de calidad se puede descargar en el sitio web de Quantimetrix en quantimetrix.com o poniéndose en contacto con el Soporte técnico en el +1 (310) 536-0006, opción 3.

Las inmersiones repetidas de algunas tiras reactivas (dipsticks) para análisis de orina en el control de Nivel 2 pueden provocar un resultado sanguíneo disminuido. Si se obtiene un resultado negativo para la sangre en el Nivel 2 antes de las 20 inmersiones o de los tres meses de apertura del vial, debe utilizarse un nuevo control. El sedimento cristalino endógeno puede estar presente y no afectar al rendimiento del producto.

Usuarios de Chemstrip/Combur/Multistix/Urocheck

Los colores producidos por las reacciones al **urobilinógeno** y/o a la **bilirrubina** en esas tiras reactivas del control de la tira reactiva para análisis de orina podrían no corresponderse con los indicados en la etiqueta del fabricante al leer visualmente las reacciones en la tira reactiva. Las reacciones de urobilinógeno son coherentes y se intensifican cuando aumenta la concentración de urobilinógeno, pero puede que no den colores exactamente iguales a los que se muestran en la etiqueta.

Nota: Siemens® CLINITEK 50 y Siemens® STATUS o CLINITEK STATUS PLUS pueden ver un resultado en la proporción de albúmina/creatinina calificado de "Anormal" con el control de Nivel 1.

Analytes Level 1 - 225851 Level 2 - 225852

Accutest® URS 10 Urine Reagent Strips (VISUAL)

| | | |
|------------------|------------------------|---|
| Leukocytes | Negative | 15 - 500 cells/ μL (Trace - Large) |
| Nitrite | Negative | Positive |
| Urobilinogen | Normal (0.2 - 1 mg/dL) | 1 - 8 mg/dL |
| Protein | Negative | 30 - 300 mg/dL (1+ - 3+) |
| pH | 5.0 - 6.5 | 7.0 - 8.5 |
| Blood | Negative | 25 - 200 cells/ μL (Small - Large) |
| Specific Gravity | 1.015 - 1.030 | 1.005 - 1.015 |
| Ketones | Negative | 5 - 160 mg/dL (Trace - Large) |
| Bilirubin | Negative | Small - Large |
| Glucose | Negative | 100 - 500 mg/dL (Trace - 2+) |

Accutest® (Analyzers)¹⁰

| | | |
|------------------|----------------------|---|
| Glucose | Negative | 100 - 1000 mg/dL (Trace - 3+) |
| Bilirubin | Negative | Small - Large |
| Ketones | Negative | 5 - $\geq 80 \text{ mg/dL}$ (Trace - Large) |
| Specific Gravity | 1.015 - ≥ 1.030 | ≥ 1.005 - 1.020 |
| Blood | Negative | 25 - 200 cells/ μL (Small - Large) |
| pH | 5.5 - 6.5 | 7.0 - 8.5 |
| Protein | Negative | 30 - $\geq 300 \text{ mg/dL}$ |
| Urobilinogen | Normal (0.2 mg/dL) | 1 - $\geq 8 \text{ mg/dL}$ |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | 15 - 500 cells/ μL (Trace - Large) |

Analytes Level 1 - 225851

Accutest® URS Reader / Visual

| | | |
|----------------------------|-------------------|--|
| Bilirubin | Negative | 1 - 4 mg/dL (1+ - 3+) (17 - 70 $\mu\text{mol/L}$) ⁸ |
| Blood | Negative | 10 - 250 Ery/ μL |
| Glucose | Negative - Normal | 20 - 1000 mg/dL (1.1 - 55.6 mmol/L) |
| Ketones | Negative | 25 - 300 mg/dL (1+ - 3+) (2.5 - 30 mmol/L) |
| Leukocytes | Negative | 25 - 500 Leu/ μL |
| Nitrite | Negative | Positive |
| pH | 5.0 - 6.5 | 7.0 - 9.0 |
| Protein | Negative | 30 - $\geq 300 \text{ mg/dL}$ (0.3 - 5.0 g/L) (1+ - 3+) |
| Specific Gravity (Density) | 1.010-1.025 | 1.000 - 1.020 |
| Urobilinogen | Normal | 2 - 8 mg/dL (34 - 100 $\mu\text{mol/L}$) ⁸ |

Beckman Coulter IRIS Diagnostics® (iChem® VELOCITY™ Analyzer)

| | | |
|------------------|----------------|---|
| Bilirubin | Not Compatible | Not Compatible |
| Urobilinogen | Normal | 2 - 4 mg/dL (1+ - 2+) |
| Ketones | Negative | Trace - 80 mg/dL (Trace - 2+) |
| Ascorbic Acid | Negative | Negative |
| Glucose | Negative | 50 - $\geq 500 \text{ mg/dL}$ (1+ - 3+) |
| Protein | Negative | 30 - $\geq 500 \text{ mg/dL}$ (1+ - 3+) |
| Blood | Negative | 0.03 - $\geq 1.0 \text{ mg/dL}$ (1+ - 3+) |
| pH | 5.0 - 7.0 | 7.0 - 9.0 |
| Nitrite | Negative | Positive ⁸ |
| Leukocytes | Negative | 75 - 500 WBC/ μL (1+ - 3+) |
| Specific Gravity | 1.017 - 1.023 | 1.010 - 1.016 |

Confirmatory and Other Tests

| | | |
|-------------------------------------|--|--|
| K-CHECK (Ketones) | Negative | Small - Large |
| Ictotest (Bilirubin) | Negative | Positive |
| Refractometer (Specific Gravity) | 1.018 - 1.024 | 1.011 - 1.017 |
| hCG | Negative | Positive |
| pH Paper | 4 - 6 | 7 - 9 |
| Sulfosalicylic Acid (Total Protein) | Negative (≤ 0.05) ¹¹ | Positive (≥ 0.50) ¹¹ |

DFI CYBOW • ComboStik • DUS Urine Reagent Strips (Visual)

| | | |
|------------------|------------------------------|--|
| Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 $\mu\text{mol/L}$) ¹³ |
| Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) |
| Bilirubin | Negative | Small~Large (1+~3+) |
| Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) |
| Specific Gravity | 1.015~1.025 | 1.005~1.020 |
| Blood | Negative | 10~250 RBC/ μL (1+~3+) |
| pH | 5~6.5 | 7~9 |
| Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | 15~500 WBC/ μL (Trace~3+) |
| Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) |
| Microalbumin | 10 mg/L | 30~150 mg/L |

DFI CYBOW R-50 (50S) • ComboStik R-50 (50S) • DUS R-50 (50S)

| | | |
|------------------|------------------------------|--|
| Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 $\mu\text{mol/L}$) ¹³ |
| Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) |
| Bilirubin | Negative | Small~Large (1+~3+) |
| Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) |
| Specific Gravity | 1.015~1.025 | 1.005~1.020 |
| Blood | Negative | 10~250 RBC/ μL (1+~3+) |
| pH | 5~6.5 | 7~9 |
| Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | 15~500 WBC/ μL (Trace~3+) |
| Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) |
| Microalbumin | 10 mg/L | 30~150 mg/L |

DFI CYBOW Reader 300 • ComboStik R-300 • DUS R-300

| | | |
|------------------|------------------------------|--|
| Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 $\mu\text{mol/L}$) ¹³ |
| Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) |
| Bilirubin | Negative | Small~Large (1+~3+) |
| Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) |
| Specific Gravity | 1.015~1.025 | 1.005~1.020 |
| Blood | Negative | 10~250 RBC/ μL (1+~3+) |
| pH | 5~6.5 | 7~9 |
| Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | 15~500 WBC/ μL (Trace~3+) |
| Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) |
| Microalbumin | 10 mg/L | 30~150 mg/L |

| Analytes | Level 1 - 225851 | Level 2 - 225852 | Analytes | Level 1 - 225851 | Level 2 - 225852 | | | |
|---|---------------------------------|--|--|-----------------------|--|--|--|--|
| DFI CYBOW Reader 600S • CombiStik R-600S• DUS R- 600S | | | | | | | | |
| Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 µmol/L) ¹³ | Bilirubin | Negative | 1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L) ⁸ | | | |
| Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) | Blood | Negative | 10 - 250 Ery/µL | | | |
| Bilirubin | Negative | Small-Large (1+~3+) | Glucose | Negative - Normal | 50 - ≥500 mg/dL (8.3 - ≥27.8 mmol/L) ⁹ | | | |
| Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) (Trace~3+) | Ketones | Negative | 25 - 300 mg/dL (1+ - 3+) (2.5 - 30 mmol/L) | | | |
| Specific Gravity | 1.015~1.025 | 1.005~1.020 | Leukocytes | Negative | 25 - 500 Leu/µL | | | |
| Blood | Negative | 10~250 RBC/µL (1+~3+) | Nitrite | Negative | Positive | | | |
| pH | 5~6.5 | 7~9 | pH | 5.0 - 7.0 | 7.0 - 9.0 | | | |
| Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) | Protein | Negative | 30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+) | | | |
| Nitrite | Negative | Positive | Specific Gravity (Density) | 1.005 - 1.025 | 1.000 - 1.020 | | | |
| Leukocytes | Negative | 15~500 WBC/µL (Trace~3+) | Urobilinogen | Normal | 2 - 12 mg/dL (34 - 200 µmol/L) ⁸ | | | |
| Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) | Ascorbic Acid | Negative | Negative | | | |
| Microalbumin | 10 mg/L | 30~150 mg/L | McKesson® (Consult Diagnostics® 10SG Urine Reagent Strips) (Visual) | | | | | |
| DFI CYBOW Reader 720 • CombiStik R-700 • DUS R- 720 | | | | | | | | |
| Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 µmol/L) ¹³ | Glucose | Negative | 100 - 1000 mg/dL (± - 3+) | | | |
| Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) | Bilirubin | Negative | 1 - 4 mg/dL (1+ - 3+) | | | |
| Bilirubin | Negative | Small-Large (1+~3+) | Ketones | Negative | 5 - 160 (± - 4+) | | | |
| Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) (Trace~3+) | Specific Gravity | 1.015 - 1.030 | 1.005 - 1.015 | | | |
| Specific Gravity | 1.015~1.025 | 1.005~1.020 | Blood | Negative | 1+ - 3+ | | | |
| Blood | Negative | 10~250 RBC/µL (1+~3+) | pH | 5.0 - 6.0 | 7.5 - 9.0 | | | |
| pH | 5~6.5 | 7~9 | Protein | Negative | 30 - 300 mg/dL (1+ - 3+) | | | |
| Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) | Urobilinogen | Normal (0.2 E.U./dL) | 1 - 8 mg/dL | | | |
| Nitrite | Negative | Positive | Nitrite | Negative | Positive | | | |
| Leukocytes | Negative | 15~500 WBC/µL (Trace~3+) | Leukocytes | Negative | 15 - 500 Leu/µL (± - 3+) | | | |
| Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) | McKesson® 120 Urine Analyzer (Consult Diagnostics 10SG Urine Reagent Strips) | | | | | |
| Microalbumin | 10 mg/L | 30~150 mg/L | Leukocytes | Negative | 70 - 500 Leu/µL (1+ - 3+) | | | |
| Fisherbrand® • Germaine AimStrip® 10SG Strips (Visual) | | | | | | | | |
| Glucose | Negative | 100 - 1000 mg/dL (± - 3+) | Nitrite | Negative | Positive | | | |
| Bilirubin | Negative | 1 - 4 (17 - 70) mg/dL (1+ - 3+) | Urobilinogen | Normal (0.2 E.U./dL) | 0.2 - 2.0 mg/dL ^{*13} | | | |
| Ketones | Negative | 5 - 160 (± - 4+) | Protein | Negative | Trace - 300 g/dL (± - 3+) | | | |
| Specific Gravity | 1.015 - 1.025 | 1.005 - 1.020 | pH | 5.0 - 6.5 | 7.0 - 9.0 | | | |
| Blood | Negative | 1+ - 3+ | Blood | Negative | 25 - 200 (1+ - 3+) | | | |
| pH | 5.0 - 6.0 | 7.5 - 9.0 | Specific Gravity | 1.020 - 1.030 | 1.005 - 1.020 | | | |
| Protein | Negative | 30 - 100 (0.3 - 1.0) mg/dL (1+ - 2+) | Ketones | Negative | 5 - 80 (Trace - 3+) | | | |
| Urobilinogen | Normal (0.2 E.U./dL) | 1 - 4 (17 - 70) mg/dL | Bilirubin | Negative | 1 - 4 mg/dL (1+ - 3+) | | | |
| Nitrite | Negative | Positive | Glucose | Negative | 100 - ≥1000 mg/dL (Trace - 3+) | | | |
| Leukocytes | Negative | 70 - 500 Leu/µL (1+ - 3+) | ROCHE VISUAL TESTING (Visual Test Strips Only) (USA) | | | | | |
| Fisherbrand® • Germaine AimStrip® 10SG Strips • Aim Urine Analyzer 2 | | | | | | | | |
| Leukocytes | Negative | 15 - 500 Leu/µL (± - 3+) | Specific Gravity | 1.015 - 1.030 | 1.000 - 1.015 | | | |
| Nitrite | Negative | Positive | pH | 5 - 7 | 7 - 9 | | | |
| Urobilinogen | Normal (0.2 E.U./dL) | 0.2 - 2.0 mg/dL ¹³ | Leukocytes | Negative | Trace - 2+ | | | |
| Protein | Negative | 30 - 100 (0.3 - 1.0) g/dL (1+ - 2+) | Nitrite | Negative | Positive | | | |
| pH | 5.0 - 6.5 | 7.0 - 9.0 | Protein | Negative | 30 - 500 mg/dL (1+ - 3+) | | | |
| Blood | Negative | 25 - 200 (1+ - 3+) | Glucose | Normal | 100 - 1000 mg/dL | | | |
| Specific Gravity | 1.025 - 1.030 | 1.005 - 1.015 | Ketones | Negative | Small - Large (1+ - 3+) | | | |
| Ketones | Negative | 5 - 80 (Trace - 3+) | Urobilinogen ^{9,*} | Normal | 1 - 12 mg/dL | | | |
| Bilirubin | Negative | 1 - 4 mg/dL (1+ - 3+) | Bilirubin ^{9,*} | Negative | 1+ - 3+ | | | |
| Glucose | Negative | 100 - 1000 mg/dL (Trace - 3+) | Blood | Negative | Trace - 250 Ery/µL | | | |
| Henry Schein OneStepPlus • Urispec Plus Analyzer (Visual) | | | | | | | | |
| Bilirubin | Negative | 1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L) ⁸ | Microalbumin ⁶ | Negative | 20 - 100 mg/L | | | |
| Blood | Negative - 10 Ery/µL | 10 - 250 Ery/µL | ROCHE Chemstrip 101 or ROCHE UriSys 1100 (USA) | | | | | |
| Glucose | Negative - Normal | 50 - ≥500 mg/dL (8.3 - ≥27.8 mmol/L) ⁹ | Blood | Negative | Trace - 250 Ery/µL (Trace - 2+) | | | |
| Ketones | Negative | 25 - 300 mg/dL (1+ - 3+) (2.5 - 30 mmol/L) | Bilirubin | Negative | 1 - 6 mg/dL (1+ - 3+)* | | | |
| Leukocytes | Negative | 25 - 500 Leu/µL | Urobilinogen | Normal | 1 - 8 mg/dL* (1+ - 3+) ⁸ | | | |
| Nitrite | Negative | Positive | Ketones | Negative | 15 - 150 mg/dL (1+ - 3+) | | | |
| pH | 5.0 - 7.0 | 7.0 - 9.0 | Glucose | Normal | 100 - 1000 mg/dL (1+ - 3+) | | | |
| Protein | Negative | 30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+) | Protein | Negative ⁷ | 30 - 500 mg/dL (1+ - 3+) | | | |
| Specific Gravity (Density) | 1.005 - 1.025 | 1.000 - 1.020 | Nitrite | Negative | Positive | | | |
| Urobilinogen | Normal | 2 - 12 mg/dL (34 - 200 µmol/L) ⁸ | Leukocytes | Negative | 25 - 500 Leu/µL (Trace - 2+) | | | |
| Ascorbic Acid | Negative | Negative | pH | 5 - 6.5 | 7 - 9 | | | |
| Henry Schein Urispec® 10SG (Visual) | | | | | | | | |
| Leukocytes | Negative | 70 - 500 Cells/µL (Small - Large) | Specific Gravity | 1.015 - 1.025 | 1.000 - 1.015 | | | |
| Nitrite | Negative | Positive | Blood | Negative | 50 - 250 Ery/µL | | | |
| Urobilinogen | Normal (0.2 E.U./dL) | 1 - 8 E.U./dL | Bilirubin | Negative | 1 - 6 mg/dL (1+ - 3+)* | | | |
| Protein | Negative | 30 - 300 mg/dL (1+ - 3+) | Urobilinogen | Normal | 1 - 8 mg/dL* (1+ - 3+) ⁸ | | | |
| pH | 5.0 - 6.0 | 7.0 - 9.0 | Ketones | Negative | 15 - 150 mg/dL (1+ - 3+) | | | |
| Blood | Negative | 25 - 200 Cells/µL (Small - Large) | Glucose | Normal | 100 - 1000 mg/dL | | | |
| Specific Gravity | 1.015 - 1.030 | 1.005 - 1.015 | Protein | Negative | Trace - 100 mg/dL (Trace - 2+) ⁸ | | | |
| Ketones | Negative | 5 - 160 mg/dL (Trace - Large) | Nitrite | Negative | Positive | | | |
| Bilirubin | Negative | Small - Large (1+ - 3+) | Leukocytes | Negative | 100 - 500 Leu/µL (1+ - 2+) | | | |
| Glucose | Negative | 100 - 500 mg/dL (Trace - 2+) | pH | 5 - 6.5 | 7 - 9 | | | |
| ROCHE cobas 6500 (cobas u 601) (USA) | | | | | | | | |
| Blood | Negative | 50 - 250 Ery/µL | Specific Gravity | 1.015 - 1.025 | 1.000 - 1.020 | | | |
| Leukocytes | Negative | 100 - 500 Leu/µL | Blood | Negative | 50 - 250 Ery/µL | | | |
| Nitrite | Negative | Positive | Leukocytes | Negative | 100 - 500 Leu/µL (1+ - 2+) | | | |
| Ketones | Negative | 15 - 150 mg/dL | Nitrite | Negative | Positive | | | |
| Glucose | Normal | 250 - 1000 mg/dL | Ketones | Negative | 15 - 150 mg/dL | | | |
| Protein | Negative ⁷ | 30 - 100 mg/dL ⁸ | Glucose | Normal | 250 - 1000 mg/dL | | | |
| Urobilinogen | Normal | 1 - 8 mg/dL ^{8*} | Protein | Negative ⁷ | 30 - 100 mg/dL ⁸ | | | |
| Bilirubin | Negative | 3 - 6 mg/dL* | Urobilinogen | Normal | 1 - 8 mg/dL* | | | |
| pH | 5 - 6 | 7 - 9 | Bilirubin | Negative | 3 - 6 mg/dL* | | | |
| Specific Gravity | 1.015 - 1.030 | 1.005 - 1.015 | pH | 5 - 6 | 7 - 9 | | | |
| Ketones | Negative | 5 - 160 mg/dL (Trace - Large) | Specific Gravity | 1.015 - 1.027 | 1.009 - 1.020 | | | |
| Bilirubin | Negative | Small - Large (1+ - 3+) | | | | | | |
| Glucose | Negative | 100 - 500 mg/dL (Trace - 2+) | | | | | | |

| Analytes | Level 1 - 225851 | Level 2 - 225852 |
|--|-----------------------------------|---------------------------------------|
| ROCHE cobas u 411 (USA) | | |
| Blood | Negative | 50 - 250 Ery/ μ L (3+ - 5+) |
| Bilirubin | Negative | 1 - 6 mg/dL (1+ - 3+)* |
| Urobilinogen | Negative - Normal | 1 - 8 mg/dL (1+ - 3+) ^{8*} |
| Ketones | Negative | 5 - 150 mg/dL (1+ - 4+) |
| Glucose | Negative - Normal | 100 - 1000 mg/dL (2+ - 4+) |
| Protein | Negative ⁷ | 30 - 500 mg/dL (2+ - 4+) ⁸ |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | 25 - 500 Leu/ μ L (1+ - 3+) |
| pH | 5 - 6.5 | 7 - 9 |
| Specific Gravity | 1.015 - 1.025 | 1.000 - 1.020 |
| ROCHE UriSys 1800 (USA) | | |
| Blood | Negative | 50 - 250 Ery/ μ L (3+ - 5+) |
| Bilirubin | Negative | 1 - 6 mg/dL (1+ - 3+)* |
| Urobilinogen | Negative - Normal | 1 - 8 mg/dL (1+ - 3+) ^{8*} |
| Ketones | Negative | 15 - 150 mg/dL (1+ - 4+) |
| Glucose | Negative - Normal | 100 - 1000 mg/dL (2+ - 4+) |
| Protein | Negative ⁷ | 75 - 500 mg/dL (2+ - 4+) ⁸ |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | 25 - 500 Leu/ μ L (1+ - 3+) |
| pH | 5 - 6.5 | 7 - 9 |
| Specific Gravity | 1.015 - 1.025 | 1.000 - 1.020 |
| Siemens® VISUAL TESTING (Visual Test Strips Only) | | |
| Glucose | Negative | 100 - 500 mg/dL |
| Bilirubin | Negative | Small - Large (1+ - 3+) |
| Ketones | Negative | 5 - 160 mg/dL (Trace - Large) |
| Specific Gravity | 1.015 - 1.025 | 1.005 - 1.020 |
| Blood | Negative | Small - Large (1+ - 3+) |
| pH | 5.0 - 6.5 | 7.5 - 8.5 |
| Protein | Negative | Trace - 300 mg/dL (Trace - 3+) |
| Urobilinogen | Normal (0.2 E.U./dL) ⁷ | 1.0 - 8.0 E.U./dL* |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | Trace - Large (Trace - 3+) |
| Creatinine ³ | 10 - 50 mg/dL | 100 - 300 mg/dL |
| Siemens® CLINITEK 50 | | |
| Glucose | Negative | 100 - ≥1000 mg/dL (Trace - 3+) |
| Bilirubin | Negative | Small - Large (1+ - 3+) |
| Ketones | Negative | Trace - ≥80 mg/dL (Trace - 3+) |
| Specific Gravity | 1.010 - ≥1.030 | ≤1.005 - 1.015 |
| Blood | Negative | Trace - Large (Trace - 3+) |
| pH | 5.0 - 6.0 | 7.0 - ≥9.0 |
| Protein | Negative | Trace - ≥300 mg/dL (Trace - 3+) |
| Urobilinogen | Normal (0.2 E.U./dL) | 1.0 - ≥8.0 E.U./dL |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | Trace - Large (Trace - 3+) |
| Microalbumin ² | 10 - 30 mg/L | 30 - 300 mg/L |
| Creatinine ⁴ | 10 - 100 mg/dL | 100 - 300 mg/dL |
| Siemens® CLINITEK 500 | | |
| Glucose | Negative | 100 - 500 mg/dL (Trace - 2+) |
| Bilirubin | Negative | Small - Large (1+ - 3+) |
| Ketones | Negative | Trace - ≥80 mg/dL (Trace - 3+) |
| Specific Gravity | 1.015 - ≥1.030 | ≤1.005 - 1.020 |
| Blood | Negative | Small - Large (1+ - 3+) |
| pH | 5.5 - 6.5 | 7.0 - ≥9.0 |
| Protein | Negative | 30 - ≥300 mg/dL (1+ - 3+) |
| Urobilinogen | Normal (0.2 E.U./dL) | 1.0 - ≥8.0 E.U./dL |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | Trace - Large (Trace - 3+) |
| Creatinine ³ | 10 - 100 mg/dL | 100 - 300 mg/dL |
| Siemens® CLINITEK ADVANTUS | | |
| Glucose | Negative | 100 - 500 mg/dL (Trace - 2+) |
| Bilirubin | Negative | Small - Large (1+ - 3+) |
| Ketones | Negative | Trace - ≥80 mg/dL (Trace - 3+) |
| Specific Gravity | 1.015 - ≥1.030 | ≤1.005 - 1.020 |
| Blood | Negative | Small - Large (1+ - 3+) |
| pH | 5.5 - 6.5 | 7.5 - ≥9.0 |
| Protein | Negative | 30 - ≥300 mg/dL (1+ - 3+) |
| Urobilinogen | Normal (0.2 E.U./dL) | 1.0 - ≥8.0 E.U./dL |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | Trace - Large (Trace - 3+) |
| Creatinine ³ | 10 - 100 mg/dL | 100 - 300 mg/dL |

| Analytes | Level 1 - 225851 | Level 2 - 225852 |
|--|----------------------|--|
| Siemens® CLINITEK STATUS or Siemens® CLINITEK STATUS PLUS or STATUS CONNECT | | |
| Glucose | Negative | 100 - 500 mg/dL (Trace - 2+) |
| Bilirubin | Negative | Small - Large (1+ - 3+) |
| Ketones | Negative | Trace - ≥160 mg/dL (Trace - 4+) |
| Specific Gravity | 1.015 - ≥1.030 | 1.010 - 1.025 |
| Blood | Negative | Small - Large (1+ - 3+) |
| pH | 5.0 - 6.5 | 7.0 - ≥9.0 |
| Protein | Negative | 30 - ≥300 mg/dL (1+ - 3+) |
| Urobilinogen | Normal (0.2 E.U./dL) | 2.0 - ≥8.0 E.U./dL |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | Trace - Large (Trace - 3+) |
| Microalbumin ² | 10 - 30 mg/L | 30 - 300 mg/L |
| Creatinine ⁴ | 10 - 100 mg/dL | 100 - 300 mg/dL |
| hCG | Negative | Positive |
| Teco Visual | | |
| Glucose | Negative | 100 - 1000 mg/dL |
| Bilirubin | Negative | Small - Large (1+ - 3+) |
| Ketones | Negative | Trace - 80 mg/dL |
| Specific Gravity | 1.010 - 1.025 | ≤1.005 - 1.020 |
| Blood | Negative | Small - Large (1+ - 3+) |
| pH | 5 - 6.5 | 7.0 - 8.5 |
| Protein | Negative | 30 - 300 mg/dL (1+ - 3+) |
| Urobilinogen | Normal (0.2 E.U./dL) | 2 - ≥8 E.U./dL |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | Small - Large (1+ - 3+) |
| Albumin | 10 - 30 mg/L | 80 - 150 mg/L |
| Creatinine | 10 - 50 mg/dL | 100 - 300 mg/dL |
| Teco Analyzers • TC-101 • TC-201 • TC-720 | | |
| Glucose | Negative | 100 - 1000 mg/dL |
| Bilirubin | Negative | Small - Large (1+ - 3+) |
| Ketones | Negative | Trace - 80 mg/dL |
| Specific Gravity | 1.010 - ≥1.030 | ≤1.005 - 1.025 |
| Blood | Negative | Small - Large (1+ - 3+) |
| pH | 5 - 6.5 | 7.0 - 8.5 |
| Protein | Negative | Trace - ≥300 mg/dL (Trace - 3+) |
| Urobilinogen | Normal (0.2 E.U./dL) | 1 - ≥8 E.U./dL |
| Nitrite | Negative | Positive |
| Leukocytes | Negative | Trace - Large (Trace - 3+) |
| Albumin | | Data Not Available at Time of Printing |
| Creatinine | | |
| Uriscan Visual • 10SGL Strips • Visual | | |
| Blood | Negative | 10 - 250 RBC/ μ L (1+ - 3+) |
| Bilirubin | Negative | 0.5 - 3.0 mg/dL (1+ - 3+) |
| Urobilinogen | 0.1 mg/dL (Negative) | 1 - 12 mg/dL (1+ - 4+) |
| Ketones | Negative | 5 - 100 mg/dL (± - 3+) |
| Protein | Negative | 30 - 300 mg/dL (1+ - 3+) |
| Nitrite | Negative | Positive |
| Glucose | Negative | 250 - 1000 mg/dL (1+ - 3+) |
| pH | 5.0 - 6.0 | 7.5 - 8.5 |
| Specific Gravity | 1.020 - 1.030 | 1.005 - 1.015 |
| Leukocytes | Negative | 25 - 500 WBC/ μ L (1+ - 3+) |
| Uriscan™ Optima Urine Analyzers • 10 SGL Strips | | |
| Blood | Negative | 10 - 250 RBC/ μ L (1+ - 3+) |
| Bilirubin | Negative | 0.5 - 3.0 mg/dL (1+ - 3+) |
| Urobilinogen | Normal (<1) | 1 - 12 mg/dL (1+ - 4+) |
| Ketones | Negative | 5 - 100 mg/dL (± - 3+) |
| Protein | Negative | 10 - 300 mg/dL (± - 3+) |
| Nitrite | Negative | Positive |
| Glucose | Negative | 100 - 2000 mg/dL (± - 4+) |
| pH | 5.0 - 6.0 | 6.5 - 8.5 |
| Specific Gravity | 1.015 - 1.030 | 1.005 - 1.020 |
| Leukocytes | Negative | 25 - 500 WBC/ μ L (1+ - 3+) |

INTERNATIONAL USE ONLY

This Section is for International Use only and contains data for methods that are not available or cleared for diagnostic use in the United States.

| Analytes | Level 1 - 225851 | Level 2 - 225852 | Analytes | Level 1 - 225851 | Level 2 - 225852 | | | |
|--|---------------------------------------|---|---|------------------------------|--|--|--|--|
| 77 Elektronika (Visual/Analyzers) | | | | | | | | |
| Bilirubin | Negative | 1 - 6 mg/dL (+ - 3+) ⁹ | Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 µmol/L) ¹³ | | | |
| Urobilinogen | Normal | 2 - 12 mg/dL (1+ - 4+) ^{9,13} | Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) | | | |
| Ketones | Negative | 5 - 150 mg/dL (1+ - 3+) | Bilirubin | Negative | Small-Large (1+-3+) | | | |
| Ascorbic Acid | Negative | Negative | Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) | | | |
| Glucose | Normal | 150 - 1000 mg/dL (2+ - 4+) | Specific Gravity | 1.015~1.025 | 1.005~1.020 | | | |
| Protein | Negative | 15 - 500 mg/dL (1+ - 3+) | Blood | Negative | 10~250 RBC/µL (1+~3+) | | | |
| Blood | Negative | 10 - 300 p/mL (1+ - 3+) | pH | 5~6.5 | 7~9 | | | |
| pH | 5 - 6 | 6 - 8 | Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) | | | |
| Nitrite | Negative | Positive | Nitrite | Negative | Positive | | | |
| Leukocytes | Negative | 75 - 500 Leu/µL (2+ - 3+) | Leukocytes | Negative | 15~500 WBC/µL (Trace~3+) | | | |
| Specific Gravity | 1.010 - 1.035 | 1.000 - 1.025 | Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) | | | |
| Creatinine | 10 - 100 mg/dL (0.9 - 8.8 mmol/L) | 50 - 300 mg/dL (4.4 - 26.5 mmol/L) | Microalbumin | 10 mg/L | 30~150 mg/L | | | |
| Microalbumin | ≤10 mg/L | 150 - 500 mg/L | DFI CYBOW R-50 (50S) • ComboStik R-50 (50S) • DUS R-50 (50S) | | | | | |
| Bilirubin | Negative | 1+ - 2+ | Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 µmol/L) ¹³ | | | |
| Urobilinogen | Normal | 2 - 12 mg/dL (35 - 200 µmol/L) ⁹ | Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) | | | |
| Ketones | Negative | (+) - 3+ | Bilirubin | Negative | Small-Large (1+-3+) | | | |
| Ascorbic Acid | Negative | Negative | Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) | | | |
| Glucose | Normal | 50 - 1000 mg/dL (2.8 - 56 mmol/L) | Specific Gravity | 1.015~1.025 | 1.005~1.020 | | | |
| Protein | Negative | 30 - 500 mg/dL | Blood | Negative | 10~250 RBC/µL (1+~3+) | | | |
| Blood | Negative ⁵ | 10 - 300 Ery/µL (1+ - 3+) | pH | 5~6.5 | 7~9 | | | |
| pH | 5 - 6 | 6 - 8 | Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) | | | |
| Nitrite | Negative ⁵ | Positive | Nitrite | Negative | Positive | | | |
| Leukocytes | Negative | 25 - 500 Leu/µL | Leukocytes | Negative | 15~500 WBC/µL (Trace~3+) | | | |
| Specific Gravity | 1.010 - 1.020 | 1.000 - 1.010 | Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) | | | |
| Creatinine | 10 - 100 mgdL (0.9 - 8.8 mmol/L) | 100 - 300 mgdL (8.8 - 26.5 mmol/L) | Microalbumin | 10 mg/L | 30~150 mg/L | | | |
| Microalbumin | 10 - 80 mg/L | 150 - 500 mg/L | DFI CYBOW Reader 300 • ComboStik R-300 • DUS R-300 | | | | | |
| Bilirubin | Negative | 1 - 4 mg/dL, 17 - 70 µmol/L, (1+ - 3+) | Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 µmol/L) ¹³ | | | |
| Urobilinogen | Normal | 2 - 12 mg/dL, 35 - 200 µmol/L, (1+ - 4+) | Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) | | | |
| Ketones | Negative | 10 - 300 mg/dL, 1.0 - 30 mmol/L, (1+ - 3+) | Bilirubin | Negative | Small-Large (1+-3+) | | | |
| Ascorbic Acid | Negative - 20 mg/dL, Negative - 1+ | Negative - 20 mg/dL, Negative - 1+ | Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) | | | |
| Glucose | Normal | 50 - 1000 mg/dL, 2.8 - 56 mmol/L, (1+ - 5+) | Specific Gravity | 1.015~1.025 | 1.005~1.020 | | | |
| Protein | Negative | 30 - 500 mg/dL, 0.3 g/L - 5 g/L, (1+ - 3+) | Blood | Negative | 10~250 RBC/µL (1+~3+) | | | |
| Blood | Negative ⁵ | 10 - 300 Ery/µL, (1+ - 3+) | pH | 5~6.5 | 7~9 | | | |
| pH | 5 - 7 | 6 - 9 | Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) | | | |
| Nitrite | Negative ⁵ | Positive | Nitrite | Negative | Positive | | | |
| Leukocytes | Negative | 25 - 500 Leu/µL (1+ - 3+) | Leukocytes | Negative | 15~500 WBC/µL (Trace~3+) | | | |
| Specific Gravity | 1.010 - 1.025 | 1.000 - 1.020 | Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) | | | |
| Creatinine | 10 - 50 mgdL (0.9 - 4.4 mmol/L) | 50 - 300 mgdL (4.4 - 26.5 mmol/L) | Microalbumin | 10 mg/L | 30~150 mg/L | | | |
| Microalbumin | 10 - 80 mg/L | 150 - 500 mg/L | DFI CYBOW Reader 600S • CombiStik R-600S • DUS R-600S | | | | | |
| Bilirubin | Negative | 1~4 mg/dL (16~66 µmol/L) ¹³ | Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 µmol/L) ¹³ | | | |
| Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 µmol/L) ¹³ | Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) | | | |
| Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) | Bilirubin | Negative | Small-Large (1+-3+) | | | |
| Bilirubin | Negative | Small-Large (1+-3+) | Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) (Trace~3+) | | | |
| Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) | Specific Gravity | 1.015~1.025 | 1.005~1.020 | | | |
| Specific Gravity | 1.015~1.025 | 1.005~1.020 | Blood | Negative | 10~250 RBC/µL (1+~3+) | | | |
| Blood | Negative | 10~250 RBC/µL (1+~3+) | pH | 5~6.5 | 7~9 | | | |
| pH | 5~6.5 | 7~9 | Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) | | | |
| Protein | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) | Nitrite | Negative | Positive | | | |
| Nitrite | Negative | Positive | Leukocytes | Negative | 15~500 WBC/µL (Trace~3+) | | | |
| Leukocytes | Negative | 15~500 WBC/µL (Trace~3+) | Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) | | | |
| Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) | Microalbumin | 10 mg/L | 30~150 mg/L | | | |
| Microalbumin | 10 mg/L | 30~150 mg/L | DfI Cybow Reader 720 • Combo Stik R-700 • DUS R-720 | | | | | |
| Leukocytes | Negative | 70 - 500 Leu/µL | Urobilinogen | Normal (0.1~1 mg/dL) | 1~4 mg/dL (16~66 µmol/L) ¹³ | | | |
| Nitrite | Negative | Positive | Glucose | Negative | 50~2000 mg/dL (2.8~111 mmol/L) | | | |
| Urobilinogen | 0.2 mg/dL | 0.2 - 2 mg/dL ¹³ | Bilirubin | Negative | Small-Large (1+-3+) | | | |
| Protein | Negative | 30 - 200 mg/dL | Ketones | Negative | 5~160 mg/dL (0.5~16 mmol/L) (Trace~3+) | | | |
| pH | 5.5 - 6.5 | 7.0 - 8.5 | Specific Gravity | 1.015~1.025 | 1.005~1.020 | | | |
| Blood | Negative | 1+ - 3+ | Blood | Negative | 10~250 RBC/µL (1+~3+) | | | |
| Specific Gravity | 1.015 - 1.030 | 1.005 - 1.025 | pH | 5~6.5 | 7~9 | | | |
| Ketones | Negative | 5 - 160 mg/dL | Protein, Total | Negative | 15~300 mg/dL (0.15~3.0 g/L) (Trace~3+) | | | |
| Bilirubin | Negative | 1 - 4 mg/dL | Nitrite | Negative | Positive | | | |
| Bilirubin | Negative | 1 - 4 mg/dL (1+ - 3+) | Leukocytes | Negative | 15~500 WBC/µL (Trace~3+) | | | |
| Glucose | Negative | 100 - 500 mg/dL | Creatinine | 10~50 mg/dL (0.5~0.9 mmol/L) | 100~300 mg/dL (8.8~26.5 mmol/L) | | | |
| Creatinine | 10 - 50 mg/dL | 50 - 300 mg/dL | Microalbumin | 10 mg/L | 30~150 mg/L | | | |
| Microalbumin | 1 - 3 mg/dL | 8 - 15 mg/dL | ERBA LACHEMA Dekaphan LAURA STRIPS & LAURA Urine Analyzer • ERBA Mannheim Uro-dip 10e Strips/ Uro-dipcheck 400e Urine Analyzer | | | | | |
| Bilirubin | Negative | 3 - 6 mg/dL (51 - 103 µmol/L) (2+ - 3+) | Bilirubin | Negative | 3 - 6 mg/dL (51 - 103 µmol/L) (2+ - 3+) | | | |
| Blood | Negative | 50 - 250 Ery/µL (2+ - 3+) | Glucose | Negative | 100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+) | | | |
| Glucose | Negative | 100 - 500 mg/dL | Ketones | Negative | 16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+) | | | |
| Creatinine | 10 - 50 mg/dL | 50 - 300 mg/dL | Leukocytes | Negative | 75 - 500 Leu/µL (2+ - 3+) | | | |
| Microalbumin | 1 - 3 mg/dL | 8 - 15 mg/dL | Nitrite | Negative | Positive | | | |

| Analytes | Level 1 - 225851 | Level 2 - 225852 | Analytes | Level 1 - 225851 | Level 2 - 225852 | | | |
|--|-----------------------|---|---|-----------------------|---------------------------------------|--|--|--|
| ERBA LACHEMA DekaPHAN LAURA STRIPS & LAURA M Urine Analyzer • ERBA Mannheim Uro-dip 10e STRIPS & LAURA M Urine Analyzer | | | | | | | | |
| Bilirubin | Negative | 3 - 6 mg/dL (51 - 103 µmol/L) (2+ - 3+) | Blood | Negative | Trace - 250 Ery/µL (Trace - 4+) | | | |
| Blood | Negative | 50 - 250 Ery/µL (2+ - 3+) | Bilirubin | Negative | 3 - 6 mg/dL (2+ - 3+)* | | | |
| Glucose | Negative | 300 - 1000 mg/dL (17 - 55 mmol/L) (3+ - 4+) | Urobilinogen | Negative - Normal | 1 - 8 mg/dL (1+ - 3+) ^{8*} | | | |
| Ketones | Negative | 16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+) | Ketones | Negative | 5 - 150 mg/dL (1+ - 3+) | | | |
| Leukocytes | Negative | 75 - 500 Leu/µL (2+ - 3+) | Glucose | Negative - Normal | 100 - 1000 mg/dL (1+ - 4+) | | | |
| Nitrite | Negative | Positive | Protein | Negative ⁷ | 25 - 500 mg/dL (1+ - 4+) ⁸ | | | |
| pH | ≤6 | 7 - 9 | Nitrite | Negative | Positive | | | |
| Protein | Negative | 30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+) | Leukocytes | Negative | 25 - 500 Leu/µL (Trace - 3+) | | | |
| Specific Gravity | 1.020 - 1.030 | 1.000 - 1.010 | pH | 5 - 6.5 | 7 - 9 | | | |
| Urobilinogen | Normal | Normal - 3 mg/dL (Normal - 51 µmol/L) (Normal - 2+) | Specific Gravity | 1.015 - 1.025 | 1.000 - 1.015 | | | |
| ERBA LACHEMA DekaPHAN LAURA STRIPS & LAURA Smart Urine Analyzer • ERBA Mannheim Uro-dip 10e STRIPS & Uro-dipcheck 240e Urine Analyzer | | | | | | | | |
| Bilirubin | Negative | 1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+) | Roche cobas u 411 (International) | | | | | |
| Blood | Negative | 10 - 250 Ery/µL (1+ - 3+) | Blood | Negative | 50 - 250 Ery/µL (3+ - 5+) | | | |
| Glucose | Negative | 100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+) | Bilirubin | Negative | 3 - 6 mg/dL (2+ - 3+)* | | | |
| Ketones | Negative | 16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+) | Urobilinogen | Negative - Normal | 1 - 8 mg/dL (1+ - 3+) ^{8*} | | | |
| Leukocytes | Negative | 75 - 500 Leu/µL (2+ - 3+) | Ketones | Negative | 15 - 150 mg/dL (1+ - 4+) | | | |
| Nitrite | Negative | Positive | Glucose | Negative - Normal | 300 - 1000 mg/dL (3+ - 4+) | | | |
| pH | 5 - 6.5 | 7 - 9 | Protein | Negative ⁷ | 15 - 500 mg/dL (1+ - 4+) ⁸ | | | |
| Protein | Negative | 30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+) | Nitrite | Negative | Positive | | | |
| Specific Gravity | 1.020 - 1.030 | 1.000 - 1.015 | Leukocytes | Negative | 100 - 500 Leu/µL (2+ - 3+) | | | |
| Urobilinogen | Normal | Normal - 3 mg/dL (Normal - 51 µmol/L) (Normal - 2+) | pH | 5 - 6.5 | 7 - 9 | | | |
| ERBA LACHEMA Dekaphan Laura Strips (Visual) • ERBA Mannheim Uro-dip 10e Strips (Visual) | | | | | | | | |
| Bilirubin | Negative | 3 - 6 mg/dL (51 - 103 µmol/L) (2+ - 3+) | Specific Gravity | 1.015 - 1.025 | 1.000 - 1.020 | | | |
| Blood | Negative | 10 - 250 Ery/µL (1+ - 3+) | ROCHE UriSys 1800 (International) | | | | | |
| Glucose | Negative | 100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+) | Blood | Negative | 50 - 250 Ery/µL (3+ - 5+) | | | |
| Ketones | Negative | 16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+) | Bilirubin | Negative | 3 - 6 mg/dL (2+ - 3+)* | | | |
| Leukocytes | Negative | 75 - 500 Leu/µL (2+ - 3+) | Urobilinogen | Negative - Normal | 1 - 8 mg/dL (1+ - 3+) ^{8*} | | | |
| Nitrite | Negative | Positive | Ketones | Negative | 15 - 150 mg/dL (1+ - 4+) | | | |
| pH | 5 - 6 | 7 - 9 | Glucose | Negative - Normal | 300 - 1000 mg/dL (3+ - 4+) | | | |
| Protein | Negative | 30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+) | Protein | Negative ⁷ | 15 - 500 mg/dL (1+ - 4+) ⁸ | | | |
| Specific Gravity | 1.020 - 1.030 | 1.000 - 1.015 | Nitrite | Negative | Positive | | | |
| Urobilinogen | Normal | 1 - 6 mg/dL (17 - 102 µmol/L) (1+ - 3+) | Leukocytes | Negative | 100 - 500 Leu/µL (2+ - 3+) | | | |
| ROCHE VISUAL TESTING (Visual Test Strips Only) (International) | | | pH | 5 - 6.5 | 7 - 9 | | | |
| Specific Gravity | 1.015 - 1.030 | 1.000 - 1.015 | Specific Gravity | 1.015 - 1.025 | 1.000 - 1.020 | | | |
| pH | 5 - 7 | 7 - 9 | SYSMEX UC-1000 Analyzer / MEDITAPE UC-10/12 S Strips | | | | | |
| Leukocytes | Negative | 75 - 500 Leu/µL | Urobilinogen | Normal | 34 - 202 µmol/L (1+ - 4+) | | | |
| Nitrite | Negative | Positive | Blood | Negative | 0.06 - 0.75 mg/dL (1+ - 3+) | | | |
| Protein | Negative | 30 - 500 mg/dL | Protein | Negative | 0.30 - 3.0 g/L (1+ - 3+) | | | |
| Glucose | Normal | 100 - 1000 mg/dL (2+ - 4+) | Glucose | Negative | 2.8 - 28 mmol/L (± - 3+) | | | |
| Ketones | Negative | 1+ - 3+ | Ketones | Negative | 10 - 30 mg/dL (1+ - 3+) | | | |
| Urobilinogen ⁹ * | Normal | 1 - 12 mg/dL (1+ - 4+) | Bilirubin | Negative | 8.6 - 34 µmol/L (1+ - 3+) | | | |
| Bilirubin ⁹ * | Negative | 1+ - 3+ | Nitrite | Negative | Positive | | | |
| Blood | Negative | 25 - 250 Ery/µL | Specific Gravity | 1.005 - 1.020 | 1.000 - 1.020 | | | |
| Microalbumin ⁶ | Negative | 20 - 100 mg/L | Leukocytes | Negative | 25 - 500 Leu/µL (1+ - 3+) | | | |
| ROCHE cobas 6500 (cobas 601) (International) | | | pH | 5.0 - 6.5 | 7.0 - 8.5 | | | |
| Blood | Negative | 50 - 250 Ery/µL | Creatinine | 0.1 - 1.0 g/L | 1.0 - 3.0 g/L | | | |
| Leukocytes | Negative | 100 - 500 Leu/µL | Albumin | 0.01 - 0.03 g/L | 0.15 g/L - Over | | | |
| Nitrite | Negative | Positive | YD URISCAN Urine Test Strips (Visual) | | | | | |
| Ketones | Negative | 15 - 150 mg/dL | Blood | Negative | 10~250 RBC/uL (1+~3+) | | | |
| Glucose | Normal | 300 - 1000 mg/dL | Bilirubin | Negative | 0.5~3.0 mg/dL (1+~3+) | | | |
| Protein | Negative ⁷ | 75 - 150 mg/dL ⁸ | Urobilinogen | Normal | 1~12 mg/dL (1+~4+) | | | |
| Urobilinogen | Normal | 1 - 8 mg/dL ^{8*} | Ketones | Negative | 10~100 mg/dL (1+~3+) | | | |
| Bilirubin | Negative | 3 - 6 mg/dL* | Protein | Negative | 30~1000 mg/dL (1+~4+) | | | |
| pH | 5 - 7 | 7 - 9 | Nitrite | Negative | Positive | | | |
| Specific Gravity | 1.015 - 1.027 | 1.009 - 1.020 | Glucose | Negative | 250~2000 mg/dL (1+~4+) | | | |
| ROCHE Miditron M (International) | | | pH | 5.0~6.5 | 6.5~8.5 | | | |
| Blood | Negative | 50 - 250 Ery/µL | Specific gravity | 1.015~1.030 | 1.005~1.025 | | | |
| Bilirubin | Negative | 3 - 6 mg/dL* | Leucocytes | Negative | 25~500 WBC/uL (1+~3+) | | | |
| Urobilinogen | Normal | 1 - 8 mg/dL ^{8*} | Ascorbic Acid | Negative | Negative | | | |
| Ketones | Negative | 15 - 150 mg/dL | YD URISCAN PRO / OPTIMA | | | | | |
| Glucose | Normal | 300 - 1000 mg/dL | Blood | Negative | 10~250 RBC/uL (1+~3+) | | | |
| Protein | Negative ⁷ | 25 - 150 mg/dL ⁸ | Bilirubin | Negative | 0.5~3.0 mg/dL (1+~3+) | | | |
| Nitrite | Negative | Positive | Urobilinogen | Normal | 1~12 mg/dL (1+~4+) | | | |
| Leukocytes | Negative | 100 - 500 Leu/µL | Ketones | Negative | 10~100 mg/dL (1+~3+) | | | |
| pH | 5 - 6.5 | 7 - 9 | Protein | Negative | 30~1000 mg/dL (1+~4+) | | | |
| Specific Gravity | 1.015 - 1.025 | 1.000 - 1.020 | Nitrite | Negative | Positive | | | |
| PAGE 7 | | | Glucose | Negative | 100~1000 mg/dL (±~3+) | | | |
| Bilirubin | Negative | 5.0~6.5 | pH | 5.0~6.5 | 6.5~8.5 | | | |
| Urobilinogen | Normal | 1~12 mg/dL (1+~4+) | Specific gravity | 1.010~1.030 | 1.005~1.025 | | | |
| Ketones | Negative | 10~100 mg/dL (1+~3+) | Leucocytes | Negative | 25~500 WBC/uL (1+~3+) | | | |
| Glucose | Normal | 30~1000 mg/dL | Ascorbic Acid | Negative | Negative | | | |
| Protein | Negative ⁷ | 25~150 mg/dL ⁸ | Microalbumin | Negative~30mg/L | 30~150mg/L | | | |
| Nitrite | Negative | Positive | Creatinine | 10~100mg/dL | 50~300mg/dL | | | |
| Leukocytes | Negative | 100~500 Leu/µL | | | | | | |
| pH | 5 - 6.5 | 7 - 9 | | | | | | |
| Specific Gravity | 1.015 - 1.025 | 1.000 - 1.020 | | | | | | |

| Analytes | Level 1 - 225851 | Level 2 - 225852 |
|--------------------------------------|------------------|-------------------------------------|
| YD URISCAN PRO II / OPTIMA II | | |
| Blood | Negative | 10~250 RBC/uL (1+~3+) |
| Bilirubin | Negative | 0.5~3.0 mg/dL (1+~3+) ^{*7} |
| Urobilinogen | Normal | 1~12 mg/dL (1+~4+) |
| Ketones | Negative | 10~100 mg/dL (1+~3+) |
| Protein | Negative | 30~1000 mg/dL (1+~4+) |
| Nitrite | Negative | Positive |
| Glucose | Negative | 100~1000 mg/dL (±~3+) |
| pH | 5.0~6.5 | 6.5~8.5 |
| Specific gravity | 1.010~1.030 | 1.005~1.025 |
| Leucocytes | Negative | 25~500 WBC/uL (1+~3+) |
| Ascorbic Acid | Negative | Negative |
| YD URISCAN Super | | |
| Blood | Negative | 10~250 RBC/uL (1+~3+) |
| Bilirubin | Negative | 0.5~3.0 mg/dL (1+~3+) ^{*7} |
| Urobilinogen | Normal | 1~12 mg/dL (1+~4+) |
| Ketones | Negative | 10~100 mg/dL (1+~3+) |
| Protein | Negative | 30~1000 mg/dL (1+~4+) |
| Nitrite | Negative | Positive |
| Glucose | Negative | 100~1000 mg/dL (±~3+) |
| pH | 5.0~6.5 | 6.5~8.5 |
| Specific gravity | 1.014~1.030 | 1.006~1.022 |
| Leucocytes | Negative | 25~500 WBC/uL (1+~3+) |
| Ascorbic Acid | Negative | Negative |
| YD URISCAN Super + | | |
| Blood | Negative | 10~250 RBC/uL (1+~3+) |
| Bilirubin | Negative | 0.5~3.0 mg/dL (1+~3+) ^{*7} |
| Urobilinogen | Normal | 1~12 mg/dL (1+~4+) |
| Ketones | Negative | 10~100 mg/dL (1+~3+) |
| Protein | Negative | 30~1000 mg/dL (1+~4+) |
| Nitrite | Negative | Positive |
| Glucose | Negative | 100~1000 mg/dL (±~3+) |
| pH | 5.0~6.5 | 6.5~8.5 |
| Specific gravity | 1.014~1.030 | 1.006~1.022 |
| Leucocytes | Negative | 25~500 WBC/uL (1+~3+) |
| Ascorbic Acid | Negative | Negative |

| | |
|--|--|
| | European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformità europea Conformidad europea |
| | Catalog No. Bestellnr. Nº de catalogue Catalogo n. Nº de catálogo |
| | Manufactured by Hergestellt von Fabriqué par Fabricato da Fabricado por |
| | Authorized Representative Bevollmächtigter Représentant agréé Rappresentante autorizzato Representante autorizado |
| | Consult instructions for use Gebrauchsanweisung beachten Consulter les instructions d'utilisation Consultare le istruzioni d'uso Consulte las instrucciones de uso |
| | Lot Number Bezeichnung Désignation du lot Número de lote Denominación de lote |
| | Caution, See Product Insert Achtung, Siehe Packungsbeilage Attention, voir notice d'utilisation Attenzione, vedere il foglietto illustrativo del prodotto Atención, consulte el folleto del producto |
| | For in vitro diagnostic use In-vitro Diagnosticum Pour diagnostic in vitro Per uso diagnostico in vitro De uso diagnóstico in vitro |
| | Temperature limitation Temperaturbegrenzungen Limites de température limiti di temperatura límite de temperatura |
| | Contents of kit Inhalt der Packung Contenu du coffret Contenuto della confezione Contenido del estuche |
| | Use by (last day of month) Verwendbar bis (letzter Tag des Monats) Utilisable jusqu'à (dernier jour du mois indiqué) Da utilizzare prima del (ultimo giorno del mese) Estable hasta (último día del mes) |



Level 1 **LOT** 225851



Level 2 **LOT** 225852



Level 1&2
Expiration Date

2024-11-30



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E-M044085B-08/23

Footnotes for values, Fußnoten für werte, Apostilles pour des valeurs, Note a piè di pagina per i valori, Notas al pie de la página para los valores

ENGLISH

- 2 Values only apply to Clinitek Microalbumin Reagent Strips when read on the Clinitek 50 and Status.
- 3 Values only apply to Multistix Pro™ Reagent Strips
- 4 Values only apply to Multistix Pro and Clinitek Microalbumin Reagent Strips when read on Clinitek Urine Analyzers.
- 5 Repeated dipping may yield false positive.
- 6 Values apply to Chemstrip® Micral Reagent Strips
- 7 Some customers may obtain false positives.
- 8 Some customers may obtain false negatives.
- 9 Atypical color.
- 10 Values apply to Siemens Clinitek 50, 500
- 11 Absorbance at 620 nm
- 12 The Urobilinogen reaction produces an atypical color which may result in a normal (0.2 E.U./dL) reading. Should this occur, a visual observation of the intensification of the pad color indicates a positive response.
- * See Limitations

DEUTSCH

- 2 Werte gelten nur für Clinitek Mikroalbumin-Reagenzstreifen wenn diese auf Clinitek 50 und Status.
- 3 Werte gelten nur für Multistix Pro™ Reagenzstreifen
- 4 Werte gelten nur für Multistix Pro und Clinitek Mikroalbumin-Reagenzstreifen, wenn diese auf Clinitek-Urin-Analysatoren gelesen werden
- 5 Das wiederholte Einstecken kann falsches Positiv erbringen
- 6 Werte gelten nur für Multistix Pro und Clinitek Mikroalbumin-Reagenzstreifen
- 7 Manche Kunden erhalten möglicherweise falsch positive Ergebnisse.
- 8 Manche Kunden erhalten möglicherweise falsch negative Ergebnisse.
- 9 Atypische Farbe.
- 10 Werte gelten nur für Siemens Clinitek 50, 500
- 11 Absorption bei 620 nm
- 12 Die Urobilinogen-Reaktion erzeugt eine atypische Farbe, die zu einem normalen Messwert (0,2 E.U./dL) führen kann. In diesem Fall kann eine positive Reaktion anhand der sichtbar veränderten Farbinhabitus des Testfeldes festgestellt werden.
- * Siehe Einschränkungen

FRANÇAIS

- 2 Valeurs s'appliquent uniquement aux bandes de réactif Clinitek micro-albumine lues sur Clinitek 50 et Status
- 3 Valeurs s'appliquent uniquement aux bandes de réactif Multistix Pro™
- 4 Valeurs s'appliquent uniquement aux bandes de réactif Multistix Pro et Clinitek micro-albumine lues sur Clinitek Analysateurs d'urine
- 5 Le plongement répété peut entraîner un résultat positif faux
- 6 Valeurs s'appliquent aux bandes de réactif Chemstrip® Micral
- 7 Certains clients sont susceptibles d'obtenir des faux positifs.
- 8 Certains clients sont susceptibles d'obtenir des faux négatifs.
- 9 Couleur atypique.
- 10 Valeurs s'appliquent uniquement aux Siemens Clinitek 50, 500
- 11 Absorption à 620 nm
- 12 La réaction de l'urobilinogène produit une couleur atypique pouvant donner lieu à une lecture normale (0,2 unité E.U./dL). Si cela se produit, l'observation visuelle de l'intensification de la couleur de la zone de test indique une réponse positive.
- * Voir Limitations

ITALIANO

- 2 I valori si riferiscono esclusivamente alle Strisce reagenti per microalbumina Clinitek lette su Clinitek 50 e Status
- 3 I valori si riferiscono esclusivamente alle Strisce reagenti Multistix Pro™
- 4 I valori si riferiscono esclusivamente alle Strisce reagenti per microalbumina Multistix Pro e Clinitek lette su Clinitek Analizzatori urine
- 5 Tuffarsi ripetutamente può rendere il positivo falso
- 6 I valori si riferiscono alle Strisce reagenti Micral Chemstrip®
- 7 Alcuni pazienti possono ottenere risultati falsi positivi.
- 8 Alcuni pazienti possono ottenere risultati falsi negativi.
- 9 Colore anomalo
- 10 Valori si riferiscono esclusivamente alle Siemens Clinitek 50, 500
- 11 Assorbimento a 620 nm
- 12 La reazione dell'urobilinogene produce un colore atipico che può determinare una lettura normale (0,2 unità E.U./dL). In questo caso, se si nota visivamente un'intensificazione del colore del cuscinoletto, questo indica una reazione positiva.
- * Vedere limiti

ESPAÑOL

- 2 Los valores son aplicables únicamente a las tiras reactivas Clinitek Microalbumin cuando se lean en equipos Clinitek 50 y Status
- 3 Los valores son aplicables únicamente a las tiras reactivas Multistix Pro™
- 4 Los valores son aplicables únicamente a las tiras reactivas Multistix Pro y Clinitek Microalbumin cuando se lean en equipos Clinitek Analizadores de orina
- 5 El sumergir repetidamente puede rendir el positivo falso
- 6 Los valores son aplicables a las tiras reactivas Chemstrip® Micral
- 7 Algunos pacientes pueden obtener resultados positivos falsos.
- 8 Algunos pacientes pueden obtener resultados negativos falsos.
- 9 Color anormal
- 10 Los valores son aplicables únicamente a las Siemens Clinitek 50, 500
- 11 Absorción a 620 nm
- 12 La reacción del urobilinógeno genera un color atípico que puede dar lugar a una lectura normal (0,2 E.U./dL). Si ocurriera esto, la respuesta es positiva si se observa visualmente una intensificación del color de la almohadilla.
- * Ver las limitaciones



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