

Quantimetrix® Dipper®

Urinalysis Dipstick Control

Level 1 & 2 **Insert Revision 04/2022**

LOT 135821
135822

REF

Level 1 & 2
Level 2

1440-01
1442-61

2022-08-31



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 2 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 ≥ 25 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 zuführen.

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

Lagerung und Stabilität

Das Urinalysesstäbchen-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 Verfalldatum 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 Verfalldatum 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 schäumen lassen. Den Verschluss abnehmen und das Teststäbchen wie eine Patientenprobe in die Kontrolltube einführen. Die Urineststäbchen 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-Teströhrchen nicht für Teststäbchen-Eintauchtests verwendet werden. Wenn ein Kontroll-Teströhrchen 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 mehrerer 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 ≥ 25 mIU/ml erzielt.

Einschränkungen

Falls der Hersteller einer Testmethode zu einem späteren Zeitpunkt Änderungen vornehmen 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 Qualitätskontrolprotokoll 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 3 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-Monats-Zeitraum für geöffnete Fläschchen ein negatives Ergebnis, sollte eine neue Kontrolle verwendet werden.

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 Urinalysesstäbchen-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**.

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 - Quite 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 ≥ 25 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. Encontrará 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 calificada de "Anormal" con el control de Nivel 1.

Analytes	Level 1 - 135821	Level 2 - 135822
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 ⁸
Protein	Negative	30 - 2000 mg/dL (1+ - 4+)
pH	5.0 - 6.5	7.0 - 8.5
Blood	Negative	25 - 200 cells/µL (Small - Large)
Specific Gravity	1.010 - 1.025	1.000 - 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 - ≥ 80 mg/dL (Trace - Large)
Specific Gravity	1.010 - ≥ 1.030	1.000 - 1.020
Blood	Negative	25 - 200 cells/µL (Small - Large)
pH	5.0 - 6.5	6.5 - 8.0
Protein	Negative	30 - ≥ 300 mg/dL
Urobilinogen	Normal (0.2 mg/dL)	2 - ≥ 8 mg/dL ⁸
Nitrite	Negative	Positive
Leukocytes	Negative	15 - 500 cells/µL (Trace - Large)

Analytes	Level 1 - 135821	Level 2 - 135822
Accustrip® URS Reader / Visual		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L) ⁸
Blood	Negative	10 - 250 Ery/µL
Glucose	Negative - Normal	20 - 1000 mg/dL (1.1 - 55.6 mmol/L)
Ketones	Negative	25 - 300mg/dL (1+ - 3+) (2.5 - 30mmol/L)
Leukocytes	Negative	25 - 500 Leu/µL
Nitrite	Negative	Positive
pH	5.5 - 6.5	7.0 - 9.0
Protein	Negative	30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+)
Specific Gravity (Density)	1.010 - 1.025	1.000 - 1.020
Urobilinogen	Normal	2 - 12 mg/dL (34 - 200 µmol/L) ⁸

Beckman Coulter IRIS Diagnostics® (iChem®VELOCITY™ Analyzer)		
Bilirubin	Negative	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 - ≥ 500 mg/dL (1+ - 3+)
Protein	Negative	30 - 500 mg/dL (1+ - 3+)
Blood	Negative	0.03 - ≥ 1.0 mg/dL (1+ - 3+)
pH	5.0 - 7.0	7.0 - 9.0
Nitrite	Negative	Positive ⁸
Leukocytes	Negative	25 - 500 WBC/µL (Trace - 3+)
Specific Gravity	1.018 - 1.024	1.012 - 1.018

Confirmatory and Other Tests		
K-CHECK (Ketones)	Negative	Small - Large
Ictotest (Bilirubin)	Negative	Positive
Refractometer (Specific Gravity)	1.020 - 1.026	1.014 - 1.020
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)	Normal~2 mg/dL(0.1~33 µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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)	Normal~2 mg/dL (0.1~33 µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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 - 135821	Level 2 - 135822
DFI CYBOW R-50 (50S) • ComboStik R-50 (50S) • DUS R-50 (50S)		
Urobilinogen	Normal (0.1~1 mg/dL)	Normal~2 mg/dL(0.1~33 µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
Specific Gravity	1.015~1.025	1.005~1.020
Blood	Negative	10~250 RBC/uL (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/uL (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 720 • CombiStik R-700 • DUS R-720		
Urobilinogen	Normal (0.1~1 mg/dL)	Normal ~ 2 mg/dL(0.1~33µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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 600S • CombiStik R-600S • DUS R-600S		
Urobilinogen	Normal (0.1~1 mg/dL)	Normal~2 mg/dL(0.1~33 µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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

Fisherbrand® • Germaine AimStrip® 10SG Strips (Visual)		
Glucose	Negative	100 - 1000 mg/dL (± - 3+)
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+)
Ketones	Negative	5 - 160 (± - 4+)
Specific Gravity	1.015 - 1.030	1.005 - 1.015
Blood	Negative	1+ - 3+
pH	5.0 - 6.5	7.5 - 9.0
Protein	Negative	30 - 2000 mg/dL (1+ - 4+)
Urobilinogen	Normal (0.2 E.U./dL)	1 - 4 mg/dL
Nitrite	Negative	Positive
Leukocytes	Negative	15 - 500 Leu/µL (± - 3+)

Fisherbrand® • Germaine AimStrip® 10SG Strips • Aim Urine Analyzer 2		
Leukocytes	Negative	15 - 500 Leu/µL (± - 3+)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	0.2 - 2.0 mg/dL ¹³
Protein	Negative	Trace - 300 g/dL (± - 3+)
pH	5.0 - 6.5	7.0 - 8.5
Blood	Negative	25 - 200 (1+ - 3+)
Specific Gravity	1.020 - 1.030	1.005 - 1.020
Ketones	Negative	5 - 80 (Trace - 3+)
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (Trace - 3+)

Analytes	Level 1 - 135821	Level 2 - 135822
Henry Schein OneStepPlus • Uriscpec Plus Analyzer (Visual)		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L) ⁹
Blood	Negative - 10 Ery/µL	10 - 250 Ery/µL
Glucose	Negative - Normal	50 - ≥500 mg/dL (2.8 - ≥27.8mmol/L) ⁹
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 - 7.0	7.0 - 9.0
Protein	Negative	30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+)
Specific Gravity (Density)	1.005 - 1.025	1.000 - 1.020
Urobilinogen	Normal	2 - 12 mg/dL (34 - 200 µmol/L) ⁸

Henry Schein Uriscpec® 10SG (Visual)		
Leukocytes	Negative	15 - 500 Cells/µL (Trace - Large)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	1 - 4 E.U./dL
Protein	Negative	30 - 300 mg/dL (1+ - 3+)
pH	5.0 - 6.5	7.5 - 8.5
Blood	Negative	25 - 200 Cells/µL (Small - Large)
Specific Gravity	1.010 - 1.030	1.000 - 1.020
Ketones	Negative	5 - 160 mg/dL (Trace - Large)
Bilirubin	Negative	Small - Large (1+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (Trace - 3+)

MACHEREY-NAGEL® URYXXON® Relax/300/500 Analyzer (Visual)		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70µmol/L) ⁸
Blood	Negative	10 - 250 Ery/µL
Glucose	Negative - Normal	50 - ≥500 mg/dL (2.8 - ≥27.8 mmol/L) ⁹
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 - 7.0	7.0 - 9.0
Protein	Negative	30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+)
Specific Gravity (Density)	1.005 - 1.025	1.000 - 1.020
Urobilinogen	Normal	2 - 12 mg/dL (34 - 200 µmol/L) ⁸

McKesson® (Consult Diagnostics®) 10SG Urine Reagent Strips (Visual)		
Glucose	Negative	100 - 1000 mg/dL (± - 3+)
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+)
Ketones	Negative	5 - 160 (± - 4+)
Specific Gravity	1.015 - 1.030	1.005 - 1.015
Blood	Negative	1+ - 3+
pH	5.0 - 6.5	7.5 - 9.0
Protein	Negative	30 - 2000 mg/dL (1+ - 4+)
Urobilinogen	Normal (0.2 E.U./dL)	1 - 12 mg/dL
Nitrite	Negative	Positive
Leukocytes	Negative	15 - 500 Leu/µL (± - 3+)

McKesson® 120 Urine Analyzer (Consult Diagnostics 10SG Urine Reagent Strips)		
Leukocytes	Negative	15 - 500 Leu/µL (± - 3+)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	0.2 - 2.0 mg/dL* ¹³
Protein	Negative	Trace - 300 g/dL (± - 3+)
pH	5.0 - 6.5	7.0 - 8.5
Blood	Negative	25 - 200 (1+ - 3+)
Specific Gravity	1.010 - 1.030	1.005 - 1.020
Ketones	Negative	5 - 80 (Trace - 3+)
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (Trace - 3+)

ROCHE VISUAL TESTING (Visual Test Strips Only) (USA)		
Specific Gravity	1.015 - 1.030	1.000 - 1.015
pH	5 - 7	7 - 9
Leukocytes	Negative	Trace - 2+
Nitrite	Negative	Positive
Protein	Negative	30 - 500 mg/dL (1+ - 3+)
Glucose	Normal	100 - 1000 mg/dL
Ketones	Negative	Small - Large (1+ - 3+)
Urobilinogen ^{9*}	Normal	1 - 12 mg/dL
Bilirubin ^{9*}	Negative	1+ - 3+
Blood	Negative	Trace - 250 Ery/µL
Microalbumin ⁶	Negative	20 - 100 mg/L

Analytes	Level 1 - 135821	Level 2 - 135822
ROCHE Chemstrip 101 or ROCHE Urisys 1100 (USA)		
Blood	Negative	Trace - 250 Ery/µL (Trace - 2+)
Bilirubin	Negative	1 - 6 mg/dL (1+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL * (1+ - 3+) ⁸
Ketones	Negative	15 - 150 mg/dL (1+ - 3+)
Glucose	Normal	100 - 1000 mg/dL (1+ - 3+)
Protein	Negative ⁷	30 - 500 mg/dL (1+ - 3+)
Nitrite	Negative	Positive
Leukocytes	Negative	25 - 500 Leu/µL (Trace - 2+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.015
ROCHE Chemstrip UA Urine Analyzer (USA)		
Blood	Negative	50 - 250 Ery/µL
Bilirubin	Negative	1 - 6 mg/dL (1+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL * (1+ - 3+) ⁸
Ketones	Negative	15 - 150 mg/dL (1+ - 3+)
Glucose	Normal	100 - 1000 mg/dL
Protein	Negative	Trace - 100 mg/dL (Trace - 2+) ⁸
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (1+ - 2+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
ROCHE cobas 6500 (cobas u 601) (USA)		
Blood	Negative	50 - 250 Ery/µL
Leukocytes	Negative	100 - 500 Leu/µL
Nitrite	Negative	Positive
Ketones	Negative	15 - 150 mg/dL
Glucose	Normal	250 - 1000 mg/dL
Protein	Negative ⁷	30 - 100 mg/dL ⁸
Urobilinogen	Normal	1 - 8 mg/dL ^{8*}
Bilirubin	Negative	3 - 6 mg/dL*
pH	5 - 6	7 - 9
Specific Gravity	1.017 - 1.027	1.011 - 1.022
ROCHE Criterion (USA)		
Blood	Negative	50 - 250 Ery/µL (2+ - 4+)
Bilirubin	Negative	1 - 6 mg/dL (1+ - 3+)*
Urobilinogen	Negative - Normal	1 - 8 mg/dL ^{8*}
Ketones	Negative	15 - 150 mg/dL (1+ - 3+)
Glucose	Negative - Normal	100 - 1000 mg/dL (1+ - 3+)
Protein	Negative ⁷	Trace - 100 mg/dL (Trace - 2+) ⁸
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (1+ - 2+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
ROCHE cobas u 411 (USA)		
Blood	Negative	50 - 250 Ery/µL (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 (1+ - 4+) ⁸
Nitrite	Negative	Positive
Leukocytes	Negative	25 - 500 Leu/µL (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/µL (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/µL (1+ - 3+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
ROCHE Urisys 2400 (USA)		
Blood	Negative	50 - 250 Ery/µL
Bilirubin	Negative	1 - 6 mg/dL*
Urobilinogen	Normal	1 - 8 mg/dL ^{8*}
Ketones	Negative	5 - 150 mg/dL
Glucose	Normal	100 - 1000 mg/dL
Protein	Negative ⁷	25 - 150 mg/dL ⁸
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL
pH	5 - 6.5	7 - 9
Specific Gravity	1.017 - 1.028	1.009 - 1.020

Analytes	Level 1 - 135821	Level 2 - 135822
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 - 1.030	1.005 - 1.020
Blood	Negative	Trace - Large (Trace - 3+)
pH	5.0 - 6.5	7.5 - 8.5
Protein	Negative	30 - 300 mg/dL (1+ - 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 - 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	5.0 - 6.5	7.0 - ≥9.0
Protein	Negative	30 - ≥300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1.0 - 4.0 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	5.0 - 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 ⁴	10 - 50 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 - 1.025
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)	1.0 - ≥8.0 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace - Large (Trace - 3+)
Creatinine ⁴	10 - 100 mg/dL	100 - 300 mg/dL
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)	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
hCG	Negative	Positive
Teco Diagnostics • Visual		
Glucose	Negative	100 - 1000 mg/dL
Bilirubin	Negative	Sm - Lg (1+ - 3+)
Ketones	Negative	Trace - 80 mg/dL
Specific Gravity	1.015 - ≥1.030	1.010 - 1.025
Blood	Negative	Small - Lg (1+ - 3+)
pH	5 - 6.5	6.5 - 8.0
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	Sm - Lg (1+ - 3+)
Teco Diagnostics TC-101 • TC-201 • TC-720 Analyzer		
Glucose	Negative	100 - 1000 mg/dL
Bilirubin	Negative	Sm - Lg (1+ - 3+)
Ketones	Negative	Trace - 80 mg/dL
Specific Gravity	1.010 - ≥1.030	1.010 - 1.020
Blood	Negative	Small - Lg (1+ - 3+)
pH	5 - 6.5	7.0 - 8.5
Protein	Negative	Trace - ≥300 mg/dL (Tr - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1 - ≥8 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Tr - Lg (Tr - 3+)
Albumin	10 - 30 mg/L	80 - 150 mg/L
Creatinine	10 - 100 mg/dL	100 - 300 mg/dL

Analytes	Level 1 - 135821	Level 2 - 135822
Uriscan™ (Visual) • 10 SGL Strips		
Blood	Negative	± - 250 RBC/µL (± - 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+) ⁸
Nitrite	Negative	Positive
Glucose	Negative	100 - 2000 mg/dL (± - 4+)
pH	5.0 - 6.0	7.0 - 8.5
Specific Gravity	1.020 - 1.030	1.005 - 1.020
Leukocytes	Negative	25 - 500 WBC/µL (1+ - 3+)
Uriscan™ Optima Urine Analyzers • 10 SGL Strips		
Blood	Negative	± - 250 RBC/µL (± - 3+)
Bilirubin	Negative	0.5 - 1.0 mg/dL (1+ - 2+)
Urobilinogen	Normal (<1)	1 - 12 mg/dL (1+ - 4+)
Ketones	Negative	5 - 100 mg/dL (± - 3+)
Protein	Negative	30 - 300 mg/dL (1+ - 3+) ⁸
Nitrite	Negative	Positive
Glucose	Negative	100 - 2000 mg/dL (± - 4+)
pH	5.0 - 6.5	7.0 - 8.5
Specific Gravity	1.015 - 1.030	1.010 - 1.020
Leukocytes	Negative	25 - 500 WBC/µL (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 - 135821	Level 2 - 135822
77 Elektronika (Visual/Analyzers)		
Bilirubin	Negative	Negative - 6 mg/dL (Negative - 3+) ⁹
Urobilinogen	Normal	2 - 12 mg/dL (1+ - 4+) ⁹
Ketones	Negative - 15 mg/dL	5 - 150 mg/dL ((+) - 3+)
Ascorbic Acid	Negative	Negative
Glucose	Normal	50 - 1000 mg/dL (2+ - 4+)
Protein	Negative	15 - 500 mg/dL (1+ - 3+)
Blood	Negative	10 - 300 p/µL (2+ - 3+)
pH	5 - 6	7 - 8
Nitrite	Negative	Positive
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Specific Gravity	1.010 - 1.030	1.000 - 1.025
Analyticon® (Combi Screen Strips Visual)		
Bilirubin	Negative	1+ - 3+
Urobilinogen	Normal	2 - 12 mg/dL (35-200 µmol/L) ⁹
Ketones	Negative	(+) - 3+
Ascorbic Acid	Negative	Negative
Glucose	Normal	50 - 1000 mg/dL (2.8 - 56 mmol/L)
Protein	Negative	30 - 500 mg/dL
Blood	Negative ⁵	10 - 300 Ery/µL (1+ - 3+)
pH	5 - 6	6 - 8
Nitrite	Negative ⁵	Positive
Leukocytes	Negative	25 - 500 Leu/µL
Specific Gravity	1.010 - 1.030	1.000 - 1.010
Creatinine	10 - 100 mg/dL (0.9 - 8.8 mmol/L)	100 - 300 mg/dL (8.8 - 26.5 mmol/L)
Microalbumin	10 - 80 mg/L	150 - 500 mg/L
Analyticon® (Combi Scan/Urlyzer)		
Bilirubin	Negative	1 - 4 mg/dL, 17-70 µmol/L, (1+ - 3+)
Urobilinogen	Normal	2 - 12 mg/dL, 35-200 µmol/L, (1+ - 4+)
Ketones	Negative	10 - 300 mg/dL, 1-30 mmol/L, (+) - 3+
Ascorbic Acid	Negative - 20 mg/dL, Negative - 1+	Negative - 20 mg/dL, Negative - 1+
Glucose	Normal	50 - 1000 mg/dL, 2.8 - 56 mmol/L, (1+ - 5+)
Protein	Negative	30 - 500 mg/dL, 0.3 g/L - 5 g/L, (1+ - 3+)
Blood	Negative ⁵	10 - 300 Ery/µL (1+ - 3+)
pH	5 - 7	6 - 9
Nitrite	Negative ⁵	Positive
Leukocytes	Negative	25 - 500 Leu/µL (1+ - 3+)
Specific Gravity	1.010 - 1.030	1.000 - 1.025
Creatinine	10 - 50 mg/dL (0.9 - 4.4 mmol/L)	50 - 300 mg/dL (4.4 - 26.5 mmol/L)
Microalbumin	10 - 80 mg/L	150 - 500 mg/L

Analytes	Level 1 - 135821	Level 2 - 135822
CYPRESS DIAGNOSTICS Urine Strips • CYANStrip • CYANStrip Mini (Visual)		
Urobilinogen	Normal (0.1~1 mg/dL)	Normal ~ 2 mg/dL (0.1~33 µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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	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
DiaLab Urine Strip Analyzer 500 • Urine Strip 10C • Urine Strip 2MC		
Leukocytes	Negative	70 - 500 Leu/µL
Nitrite	Negative	Positive
Urobilinogen	0.2 - 1 mg/dL	0.2 - 4 mg/dL ¹³
Protein	Negative	30 -300 mg/dL
pH	5.5 - 6.5	7.5 - 8.5
Blood	Negative	1+ - 3+
Specific Gravity	1.015 - 1.025	1.010 - 1.025
Ketones	Negative	5 - 160 mg/dL
Bilirubin	Negative	1 - 4 mg/dL
Glucose	Negative	100 - 500 mg/dL
Creatinine	10 - 50 mg/dL	50 - 200 mg/dL
Microalbumin	1 - 3 mg/dL	3 - 15 mg/dL
DFI CYBOW • ComboStik • DUS Urine Reagent Strips (Visual)		
Urobilinogen	Normal (0.1~1 mg/dL)	Normal~2 mg/dL (0.1~33 µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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)	Normal ~2 mg/dL (0.1~33µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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)	Normal ~ 2 mg/dL(0.1~33µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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 - 135821	Level 2 - 135822
DFI CYBOW Reader 600S • CombiStik R-600S • DUS R- 600S		
Urobilinogen	Normal (0.1~1 mg/dL)	Normal ~ 2 mg/dL(0.1~33µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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 - 135821	Level 2 - 135822
DFI Cybow Reader 720 • Combo Stik R-700 • DUS R-720		
Urobilinogen	Normal (0.1~1 mg/dL)	Normal~2 mg/dL(0.1~33µmol/L) ¹³
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~40 mg/dL (0.5~4 mmol/L) (Trace~2+)
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 - 135821	Level 2 - 135822
ERBA LACHEMA DekapHAN LAURA STRIPS & LAURA Urine Analyzer • ERBA Mannheim Uro-dip 10e Strips/ Uro-dipcheck 400e Urine Analyzer		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 300 mg/dL (5.5 - 17 mmol/L) (2+ - 3+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6.5	6.5 - 8
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.015 - 1.030	1.000 - 1.015
Urobilinogen	Normal	1 - 12 mg/dL (17 - 203 µmol/L) (1+ - 4+)

Analytes	Level 1 - 135821	Level 2 - 135822
ERBA LACHEMA DekapHAN LAURA STRIPS & LAURA M Urine Analyzer • ERBA Mannheim Uro-dip 10e STRIPS & LAURA M Urine Analyzer		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+)
Ketones	Negative	5.2 - 156 mg/dL (0.5 - 15 mmol/L) (± - 3+)
Leukocytes	Negative	25 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	≤6	≤6 - 8
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.010 - 1.030	1.000 - 1.015
Urobilinogen	Normal	1 - 12 mg/dL (17 - 203 µmol/L) (1+ - 4+)

Analytes	Level 1 - 135821	Level 2 - 135822
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+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 300 mg/dL (5.5 - 17 mmol/L) (2+ - 3+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6.5	6.5 - 8
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.015 - 1.030	1.000 - 1.015
Urobilinogen	Normal	1 - 12 mg/dL (17 - 203 µmol/L) (1+ - 4+)

Analytes	Level 1 - 135821	Level 2 - 135822
ERBA LACHEMA DekapHAN LAURA STRIPS (Visual) • ERBA Mannheim Uro-dip 10e STRIPS (Visual)		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 300 mg/dL (5.5 - 17 mmol/L) (2+ - 3+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6.5	6.5 - 8
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.015 - 1.030	1.000 - 1.015
Urobilinogen	Normal	1 - 12 mg/dL (17 - 203 µmol/L) (1+ - 4+)

Analytes	Level 1 - 135821	Level 2 - 135822
ROCHE VISUAL TESTING (Visual Test Strips Only) (International)		
Specific Gravity	1.015 - 1.030	1.000 - 1.015
pH	5 - 7	7 - 9
Leukocytes	Negative	10 - 500 Leu/µL
Nitrite	Negative	Positive
Protein	Negative	30 - 500 mg/dL
Glucose	Normal	100 - 1000 mg/dL (2+ - 4+)
Ketones	Negative	1+ - 3+
Urobilinogen ^{9*}	Normal	1 - 8 mg/dL (1+ - 3+)
Bilirubin ^{9*}	Negative	1+ - 3+
Blood	Negative	25 - 250 Ery/µL
Microalbumin ⁶	Negative	20 - 100 mg/L

Analytes	Level 1 - 135821	Level 2 - 135822
ROCHE cobas 6500 (cobas u 601) (International)		
Blood	Negative	50 - 250 Ery/µL
Leukocytes	Negative	100 - 500 Leu/µL
Nitrite	Negative	Positive
Ketones	Negative	15 - 150 mg/dL
Glucose	Normal	300 - 1000 mg/dL
Protein	Negative ⁷	75 - 150 mg/dL ⁸
Urobilinogen	Normal	1 - 8 mg/dL ^{8*}
Bilirubin	Negative	3 - 6 mg/dL [*]
pH	5 - 7	7 - 9
Specific Gravity	1.017 - 1.027	1.011 - 1.022

Analytes	Level 1 - 135821	Level 2 - 135822
ROCHE Miditron M (International)		
Blood	Negative	50 - 250 Ery/µL
Bilirubin	Negative	3 - 6 mg/dL [*]
Urobilinogen	Normal	1 - 8 mg/dL ^{8*}
Ketones	Negative	15 - 150 mg/dL
Glucose	Normal	300 - 1000 mg/dL
Protein	Negative ⁷	25 - 150 mg/dL ⁸
Nitrite	Negative	Positive
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 - 135821	Level 2 - 135822
ROCHE Miditron Junior (International)		
Blood	Negative	50 - 250 Ery/µL (3+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+) [*]
Urobilinogen	Negative - Normal	1 - 8 mg/dL (1+ - 3+) ^{8*}
Ketones	Negative	15 - 150 mg/dL (1+ - 4+)
Glucose	Negative - Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative ⁷	25 - 150 mg/dL (1+ - 3+) ⁸
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020

Analytes	Level 1 - 135821	Level 2 - 135822
ROCHE Urisys 1100 or Roche Urilux S (International)		
Blood	Negative	Tr - 250 Ery/µL (Tr - 4+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 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 (1+ - 4+)
Protein	Negative ⁷	25 - 500 mg/dL (1+ - 4+) ⁸
Nitrite	Negative	Positive (1+)
Leukocytes	Negative	25 - 500 Leu/µL (Trace - 3+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.015

Analytes	Level 1 - 135821	Level 2 - 135822
ROCHE Urisys 1800 or Roche cobas u 411 (International)		
Blood	Negative	50 - 250 Ery/µL (3+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+) [*]
Urobilinogen	Negative - Normal	1 - 8 mg/dL (1+ - 3+) ^{8*}
Ketones	Negative	15 - 150 mg/dL (1+ - 4+)
Glucose	Negative - Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative ⁷	75 - 500 mg/dL (2+ - 4+) ⁸
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020

Analytes	Level 1 - 135821	Level 2 - 135822
ROCHE Urisys 2400 (International)		
Blood	Negative	50 - 250 Ery/ μ L
Bilirubin	Negative	3 - 6 mg/dL
Urobilinogen	Normal	1 - 4 mg/dL ^{8*}
Ketones	Negative	15 - 150 mg/dL
Glucose	Normal	100 - 1000 mg/dL
Protein	Negative ⁷	25 - 150 mg/dL ⁸
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/ μ L
pH	5 - 6.5	7 - 9
Specific Gravity	1.017 - 1.028	1.009 - 1.020
SYSMEX UC-1000 Analyzer / MEDITAPE UC-10/125 Strips		
Urobilinogen	Normal	34 - 202 μ mol/L (1+ - 4+)
Blood	Negative	0.06 - 0.75 mg/dL (1+ - 3+)
Protein	Negative	0.30 - 3.0 g/L (1+ - 3+)
Glucose	Negative	2.8 - 14 mmol/L (\pm - 2+)
Ketones	Negative	10 - 80 mg/dL (1+ - 3+)
Bilirubin	Negative	8.6 - 34 μ mol/L (1+ - 3+)
Nitrite	Negative	Positive
Specific Gravity	1.005 - 1.020	1.005 - 1.015
Leukocytes	Negative	25 - 500 Leu/ μ L (1+ - 3+)
pH	5.0 - 6.5	7.0 - 8.0
Creatinine	0.1 - 1.0 g/L	0.5 - 2.0 g/L
Albumin	0.01 - 0.03 g/L	0.15 g/L - Over
YD URISCAN Urine Test Strips (Visual)		
Blood	Negative	10-250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5-3.0 mg/dL (1+~3+)
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	250-2000 mg/dL (1+~4+)
pH	5.0-6.5	7.0-9.0
Specific gravity	1.015-1.030	1.005-1.020
Leucocytes	Negative	25-500 WBC/uL (1+~3+)
Ascorbic Acid	Negative	Negative
YD URISCAN PRO / OPTIMA		
Blood	Negative	10-250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5-3.0 mg/dL (1+~3+)
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	250-2000 mg/dL (1+~4+)
pH	5.0-6.5	6.5-8.5
Specific gravity	1.015-1.030	1.005-1.020
Leucocytes	Negative	25-500 WBC/uL (1+~3+)
Ascorbic Acid	Negative	Negative
Microalbumin	Negative~30 mg/L	30-150 mg/L
Creatinine	10-100 mg/dL	100-300 mg/dL
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	250-2000 mg/dL (1+~4+)
pH	5.0-6.5	6.5-8.5
Specific gravity	1.010-1.030	1.005-1.020
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	100-2000 mg/dL (1+~4+)
pH	5.0-6.5	6.5-8.5
Specific gravity	1.017-1.030	1.010-1.021
Leucocytes	Negative	25-500 WBC/uL (1+~3+)
Ascorbic Acid	Negative	Negative
YD URISCAN Super Plus		
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 (\pm -3+)
pH	5.0-6.5	6.5-8.5
Specific gravity	1.017-1.030	1.011-1.022
Leucocytes	Negative	25-500 WBC/uL (1+~3+)
Ascorbic Acid	Negative	Negative

	European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformità europea Conformidad europea
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	Manufactured by Herstellt von Fabriqué par Fabricado 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 l'uso Consulte las instrucciones de uso
	Lot Number Bezeichnung Designation du lot Numero di lotto Denominación de lote
	Caution, See Product Insert Achtung, Siehe Packungsbeilage Attention, voir notice d'utilisation Attenzione, vedere il foglietto illustrativo del prodotto Attenzione, 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 Contenido della confezione Contenido del estuche
	Use by (last day of month) Verwendbar bis (letzter Tag des Monats) Utilisable jusqu'à (dernier jour du mois indique) Da utilizzare prima del (ultimo giorno del mese) Estable hasta (ultimo día del mes)

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

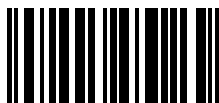
ENGLISH
 2 Values only apply to Clinitek Microalbumin Reagent Strips when read on the Clinitek 50 and Status.
 3 Values only apply to Multistix Pro™ Reagent Strips
 4 Values only apply to Multistix Pro and Clinitek Microalbumin Reagent Strips when read on Clinitek Urine Analyzers.
 5 Repeated dipping 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 only apply to Siemens Clinitek 50, 500
 11 Absorbance at 620 nm
 13 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 Eintauchen kann falsches Positiv erbringen
 6 Werte gelten für Chemstrip® Micral 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
 13 Die Urobilinogen-Reaktion erzeugt eine atypische Farbe, die zu einem normalen Messwert (0,2 EU/dl) führen kann. In diesem Fall kann eine positive Reaktion anhand der sichtbar veränderten Farbintensität 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 Analyseurs d'urine
 5 Les plongement répété peut rapporter le 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 Absorbance à 620 nm
 13 La réaction de l'urobilinogène produit une couleur atypique pouvant donner lieu à une lecture normale (0,2 UE/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 ripetuto 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 atipico
 10 I valori si riferiscono esclusivamente alle Siemens Clinitek 50, 500
 11 Assorbanza a 620 nm
 13 La reazione dell'urobilinogeno produce un colore atipico che può determinare una lettura normale (0,2 U.E./dl). In questo caso, se si nota visivamente un'intensificazione del colore del cuscinetto, questo indica una reazione positiva.
 * Vedere limiti

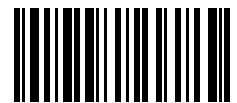
ESPAÑOL
 2 Los valores son aplicables únicamente a las tiras reactivas Clinitek Microalbumin cuando se leen en equipos Clinitek 50 y Status
 3 Los valores son aplicables únicamente a las tiras reactivas Multistix Pro™
 4 Los valores son aplicables únicamente a las tiras reactivas Multistix Pro y Clinitek Microalbumin cuando se leen en equipos Clinitek Analizadores de orina
 5 El sumergir repetido 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 Absorbancia a 620 nm
 13 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



Level 1 **LOT** 135821



Level 2 **LOT** 135822



Level 1&2
Expiration Date

2022-08-31



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E-M044082B-04/22



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