CHROMASCOPICS®
Urinalysis Control with Microscopics / **Level 1&2**

Quantimetrix

LOT 54011 54012 REF 1540-02 2019-11 CE IVD 2°C 8 °C

CE	LOT		IVD		Cont.	REF		EC REP			
European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformità europea Conformidad europea	Lot Number Bezeichnung Désignation du lot Numero di lotto Denominación de lote	Manufactured by Hergestellt von Fabriqué par Fabbricato da Fabricado por	For in vitro diagnostic use In-vitro Diagnosticum Pour diagnostic in vitro Per uso diagnostico in vitro De uso diagnóstico in vitro	Biological Risk Biogefährdung Risque biologique Rischio biologico Peligro biológico	Contents of kit Inhalt der Packung Contenu du coffret Contenuto della confezione Contenido del estuche	Catalog No. Bestellnr. N° de catalogue Catalogo n. N° de catálogo	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	Authorized Representative Bevollmächtigter Représentant agréé Rappresentante autorizzato Representante autorizado	Temperature limitation Temperaturbegrenzungen Limites de température limiti di temperatura límite de temperatura	Consult instructions for use Gebrauchsanweisung beachten Consulter les instructions d'utilisation Consultare le istruzioni l'uso Consulte las instrucciones de uso	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 (ultimo día del mes)

English

Intended Use
The Quantimetrix Chromascopics Urinalysis Control with Microscopics is intended as an assayed quality control for the Siemens Clinitek Novus Automated Urine Chemistry Analyzer. It is also compatible with Siemens urinalysis dipsticks and Clinitek analyzers, confirmatory tests such as **K-CHECK** and **Ictotest®** reagent tablets, and qualitative **hCG** methods.

In addition, Chromascopics may also be used as a means of validating the processing and centrifugation of patient urine samples prior to the microscopic evaluation of urine sediment.

Summary and Explanation
Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intra-laboratory parameters for accuracy and precision of the test method.

Microscopic QC controls must be run each day the test is performed.[1] Standardized microscopic evaluation of urine sediment is an important part of routine analysis of urine. Along with physical and chemical analysis, microscopic examination of urine can provide valuable information regarding not only renal and urinary tract disease, but also metabolic diseases unrelated to the kidney.[2] Urinary sediment microscopy generally includes the detection and identification of red blood cells, leukocytes, epithelial cells, bacteria, casts, and crystals.[3,4]

Product Description
Chromascopics is supplied as a liquid, ready-to-use control in two levels, configured with 2x120 mL of each level per box. It does not require reconstitution or dilution. They are prepared from human urine to which stabilized human red and white blood cells, calcium oxalate crystals, non-pathogenic bacteria, and other compounds have been added to produce the desired reactions when tested by the methods indicated in the **Intended Use** section. Preservatives have been added to inhibit microbial growth.

Caution
POTENTIAL BIOHAZORDOUS MATERIAL. 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,
1,3,3-Trimethyl-2-[(2-methyl-3H-indol-3-ylidene)ethylidene]indoline monohydrochloride,
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 Chromascopics Urinalysis Control with Microscopics 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 opening, the controls will remain stable until the expiration date stated on the label when stored at 2°C–8°C between uses. Discard the control if it becomes more turbid or develops a stronger odor. Discard controls in the same manner as other biological specimens, according to local guidelines.

Prior to use remove the controls from the refrigerator and replace the cap on the control bottle with the spout cap included in the control box. Allow the control to come to room temperature (18°C–25°C) for approximately 15-30 minutes depending on the volume remaining in the bottle. Mix the controls thoroughly by inverting the bottle at least 20 times to assure homogeneity of the contents. Avoid foaming. Thorough mixing with each use is important in order to obtain reproducible results. Immediately after dispensing close the spout cap and store the controls at 2°C–8°C when not in use.

Procedure for Urinalysis and Microscopic Evaluation of Urine Sediment
For the Siemens Clinitek Novus and Atlas systems follow the manufacturer's instructions for control material. For Siemens Semi-Automated and POC urinalysis systems and for visual testing dispense the control into a tube and test as if it was a patient specimen. Read the urinalysis reagent strips, visually or with an instrumental reader, in accordance with the manufacturer's instructions.

For manual microscopic evaluation of urine sediment, treat the controls as you would patient samples in accordance with the manufacturer's instructions for the standardized microscopic urinalysis system you are using. The National Committee for Clinical Laboratory Standards (NCCLS) recommends the use of standardized systems in order to yield standardized, reproducible results and to enable the reporting of abnormal sediment elements per unit volume.[1]

Procedure for hCG Tests and Confirmatory Tests
Note: The bottles of Level 1 Control are to be used as negative controls for hCG methods. The bottles of Level 2 Control are to be used as positive controls for hCG methods. Use the negative and positive controls as if they were patient specimens in accordance with the test kit manufacturer's instructions.

Most manufacturers of pregnancy test kits specify the volume of sample to be used with their kits. Many kits include transfer pipets to be used to deliver a certain sample volume onto the test device. It is important that sufficient volume be used to produce the correct test result.

If dispensing the control for hCG tests and confirmatory tests directly from the control bottles, each user should validate that the volume (number of drops) dispensed by the included spout cap is sufficient to meet the pregnancy test kit's and confirmatory tests' requirement for sample volume.

If using the same bottle of control dispensed for urinalysis testing and microscopic evaluation, remove the volume of sample to be used for hCG tests and confirmatory tests after centrifugation, before discarding the supernatant and without disturbing the sediment.

Expected Values
All expected value ranges and assignments are determined using pooled data from the system manufacturer and/or internal data generated as per the manufacturer's instructions.

Limitations
After running Chromascopics on the Siemens Clinitek Novus Automated Urine Chemistry Analyzer, the operator must clean the SG well. This is accessible via the System Function Bar on the home screen. Refer to the Siemens Clinitek Novus Automated Urine Chemistry Analyzer Operators Manual for detailed instructions.

Chromascopics contains a non-hazardous dye. If spilled it may stain some surfaces. Bleach will remove the dye from most surfaces.

Chromascopics is primarily intended for use with the Siemens Clinitek Novus Automated Urine Chemistry Analyzer. It also has been demonstrated to be compatible with the other products as stated in the **Intended Use** section. For all other urinalysis test methods please consult the product descriptions on our web site.

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.

The appearance of a macroscopic crystalline precipitate in the product will not affect performance.

Multistix 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.

References | Bibliographiee | Références | Bibliografia | Bibliografía

1 Routine Urinalysis and Collection, Transportation, and Preservation of Urine Specimens, NCCLS Documentation GP 16-A, Approved Guideline, (1995), NCCLS, Wayne PA, 19087.
2 Bradley GM, Benson ES, Todd-Sanford Clinical Diagnosis by Laboratory Methods, 15th ed., Philadelphia, PA: Saunders, 1974.
3 Bologna, CV, Understanding Laboratory Medicine, St. Louis, MO: CV Mosby Co., 1971.
4 Dudas HC, Lab Med, 12:765, 1981.

Analytes/Method	Level 1 - 54011	Level 2 - 54012	Units
Red Blood Cells (Erythrocytes)			
KOVA® Glasstic® Slide 10 with Grids	0 - 14	15 - 122	/µL
Non-grid slides (~0.5 mL)	0 - 12	3 - 60	/hpf
Non-grid slides (~1.0 mL)	0 - 5	2 - 33	/hpf
FisherBrand UriSystem DeciSlide	0 - 6	5 - 37	/hpf
White Blood Cells (Leukocytes)			
KOVA® Glasstic® Slide 10 with Grids	0 - 12	3 - 66	/µL
Non-grid slides (~0.5 mL)	0 - 8	1 - 34	/hpf
Non-grid slides (~1.0 mL)	0 - 4	1 - 16	/hpf
FisherBrand UriSystem DeciSlide	0 - 5	2 - 23	/hpf

Analytes/Method	Level 1 - 54011	Level 2 - 54012
Casts		
KOVA® Glasstic® Slide 10 with Grids	none	none
Non-grid slides (~0.5 mL)	none	none
Non-grid slides (~1.0 mL)	none	none
FisherBrand UriSystem DeciSlide	none	none
Crystals (calcium oxalate dihydrate with some monohydrate and amorphous forms) [12]		
KOVA® Glasstic® Slide 10 with Grids	none	present
Non-grid slides (~0.5 mL)	none	present
Non-grid slides (~1.0 mL)	none	present
FisherBrand UriSystem DeciSlide	none	present
Bacteria		
KOVA® Glasstic® Slide 10 with Grids	may be present	present
Non-grid slides (~0.5 mL)	may be present	present
Non-grid slides (~1.0 mL)	may be present	present
FisherBrand UriSystem DeciSlide	may be present	present

CHROMASCOPICS® Urinalysis Control with Microscopics / **Level 1&2**

Analytes	Level 1 - 54011	Level 2 - 54012
Confirmatory and Other Tests		
K-CHECK (Ketones)	Negative	Small - Large
Ictotest (Bilirubin)	Negative	Positive
Refractometer (Specific Gravity)	1.020 - 1.026	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])
SIEMENS VISUAL TESTING (Visual Test Strips Only)		
Glucose	Negative	100 - 500 mg/dL (Trace - 2+)
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	Small - Large (1+ - 3+)
pH	5.0 - 6.5	7.0 - 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 - 100 mg/dL	100 - 300 mg/dL
SIEMENS CLINITEK 50		
Glucose	Negative	100 - 500 mg/dL (Trace - 2+)
Bilirubin	Negative	Small to Large (1+ - 3+)
Ketones	Negative	5 - ≥80 mg/dL (Trace - 3+)
Specific Gravity	1.010 - ≥1.030	≤1.005 - 1.020
Blood	Negative - Trace	Trace - Large (Trace Intact - 3+)
pH	5.0 - 6.0	7.5 - 8.5
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 - 150 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	5 - ≥80 mg/dL (Trace - 3+)
Specific Gravity	1.015 - 1.025	≤1.005 - 1.015
Blood	Negative - Trace	Small - Large (1+ - 3+)
pH	5.0 - 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 [4]	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	5 - ≥80 mg/dL (Trace - 3+)
Specific Gravity	1.010 - ≥1.030	≤1.005 - 1.015
Blood	Negative - Trace	Small - Large (1+ - 3+)
pH	5.0 - 6.5	7.5 - ≥9
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+)
Creatinine [4]	10 - 100 mg/dL	100 - 300 mg/dL
SIEMENS CLINITEK STATUS • SIEMENS CLINITEK STATUS PLUS		
Glucose	Negative	100 - 500 mg/dL (Trace - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	5 - ≥160 mg/dL (1+ - 4+)
Specific Gravity	1.010 - ≥1.030	1.005 - 1.025
Blood	Negative - Trace	Small - Large (1+ - 3+)
pH	5.0 - 6.0	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+)
Microalbumin [2]	10 - 30 mg/L	30 - 150 mg/L
Creatinine [4]	10 - 100 mg/dL	100 - 300 mg/dL
hCG	Negative	Positive

Analytes	Level 1 - 54011	Level 2 - 54012
SIEMENS CLINITEK Novus		
Bilirubin	Negative	Small - Large (1+ - 3+)
Blood	Negative	Small - Large (1+ - 3+)
Glucose	Negative	250 - >=1000 (1+ - 3+)
Ketones	Negative	Trace - >=160 (Trace - +4)
Leukocytes	Negative	Trace - Large (Trace - 3+)
Nitrite	Negative	Positive
pH	5.0 - 6.5	7.5 - 8.5
Protein	Negative	30 - 300 (1+ - 3+)
Specific Gravity	1.021 - 1.027	1.012 - 1.018
Urobilinogen	Normal (0.2 E.U./dL)	1.0 - 4.0 E.U./dL
Color	≤ Dark Yellow	≤ Orange
Clarity	≤ Slightly Cloudy	≤ Slightly Cloudy

Footnotes for values

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
7 Some customers may obtain false positives.
11 Absorbance at 620 nm
12 Calcium oxalate dihydrate with some monohydrate and amorphous forms
* See Limitations

Level 1

LOT 54011

Level 2

LOT 54012

Level 1&2 Expiration Date

2019-11

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