

# CombiScreen® DIP Check



Catalog No. 93010 2 x 15 mL

Lot No.  
Expiry

Y 525  
2020/05

GB

## Intended Use

FOR IN VITRO DIAGNOSTIC USE

CombiScreen® DIP Check is intended for use as an assayed quality control material for various urinalysis reagent strips and qualitative hCG methods.

## Summary and Explanation

The use of quality control materials to objectively monitor the accuracy and precision of procedures is well established in clinical laboratories. CombiScreen® DIP Check is provided at two levels to assist in the monitoring of analytical systems within the clinical range.

## Product Description

CombiScreen® DIP Check is human urine-based containing constituents of human and animal origin as well as purified chemicals. Preservatives and stabilizers have been added to maintain product integrity. CombiScreen® DIP Check is a ready-to-use liquid control requiring no reconstitution.

## Warnings and Precautions

For in vitro diagnostic use.



### Human source material. Treat as potentially infectious.

Each donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

This product contains 0.09% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive compounds. Flush with excess water upon disposal.

The material safety data sheet contains further safety-related information. It is available for download from our homepage <http://www.analyticon-diagnostics.com>.

### Indications of deterioration

If the controls are turbid or if any evidence of microbial growth or contamination is present, the controls should be discarded. This should be done according to the local guidelines in the same manner as for other biological specimens.

## Storage and Stability

CombiScreen® DIP Check is stable until the expiration date on the tube label when stored unopened at 2–8°C. Do not freeze.

Once opened, tubes of control are stable for 75 days when stored tightly capped at 2–8°C or 20 dipstick immersions have taken place, whichever occurs first. CombiScreen® DIP Check may be stored for 30 days at 20–25°C.

## Procedure

CombiScreen® DIP Check should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system (instrument, kit, or reagent) being used. Allow the product to reach room temperature prior to use.

QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

### Instructions

1. Gently invert the tube several times before sampling to ensure homogeneity. This is important to obtain reproducible results.
2. For dipstick testing: remove the cap and dip the reagent strip in the tube as if it were a patient sample. In accordance with the manufacturer's instructions, read the reagent strips either visually or with an instrument reader.

*For hCG testing:* In accordance with the hCG test kit manufacturer's instructions, use controls as if they were patient specimens. For the control of confirmatory pregnancy test kits, be sure to use the transfer pipette included in the kit to deliver the correct sample amount to test device.

3. Replace the cap immediately after use and store appropriately.

### Materials provided

1x Control L1, 15 ml



1x Control L2, 15 ml



1x Kit insert

## Limitations of the Procedure

CombiScreen® DIP Check should not be used past the expiration date on the tube label. CombiScreen® DIP Check is a stabilized liquid product. To obtain consistent assay values, CombiScreen® DIP Check requires storage and handling as detailed in *Storage and Stability*.

Accurate and reproducible results are dependent upon properly functioning instruments and reagents. The ranges given are intended only as a guideline. Each laboratory should establish their own acceptable ranges and tolerance limits based on their test system.

## Expected readings

The expected values printed in this insert were derived from replicate analyses of representative samples of the product and are specific to this lot of CombiScreen® DIP Check. Testing data used to establish the expected values were derived from multiple instruments. All values have been assigned with manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these expected values. To request a faxed or emailed copy of the value assignment, contact your local distributor or [info@analyticon-diagnostics.com](mailto:info@analyticon-diagnostics.com).



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Analyticon CombiScreen® Urine Test Strips				
Analyte	Visual		Instrumental (Analyticon CombiScan® / Urilyzer®)	
	Level L1	Level L2	Level L1	Level L2
Ascorbic Acid	Negative	Negative	Negative – 20 mg/dl Negative – 1+	Negative – 20 mg/dl Negative – 1+
Bilirubin	Negative	1+ – 3+	Negative	1 – 4 mg/dl 17 – 70 µmol/l 1+ – 3+
Blood	Negative *)	10 – 300 Ery/µl 1+ – 3+	Negative *)	10 – 300 Ery/µl 1+ – 3+
Glucose	Normal	50 – 1000 mg/dl 2.8 – 56 mmol/l	Normal	50 – 1000 mg/dl 2.8 – 56 mmol/l 1+ – 5+
Ketones	Negative	(+) – 3+	Negative	10 – 300 mg/dl 1.0 – 30 mmol/l (+) – 3+
Leucocytes	Negative	25 – 500 Leu/µl	Negative	25 – 500 Leu/µl 1+ – 3+
Nitrite	Negative *)	Positive	Negative *)	Positive
pH	5 – 6	7 – 9	5 – 7	6 – 9
Protein	Negative	30 – 500 mg/dl	Negative	30 – 500 mg/dl 0.3 – 0.5 g/l 1+ – 3+
Specific Gravity	1.020 – 1.030	1.000 – 1.015	1.015 – 1.030	1.000 – 1.030
Urobilinogen	Normal	2 – 12 mg/dl (**) 35 – 200 µmol/l	Normal	2 – 12 mg/dl 35 – 200 µmol/l 1+ – 4+

\*) Repeated dipping may yield false positives.

\*\*\*) Atypical color may occur.

	Level N (L1)	Level P (L2)
Analyticon Urilyzer® 100		



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Siemens Multistix® 10SG Urinalysis Reagent Strips				
Analyte	Visual		Instrumental (Siemens Clinitek® Status® / Advantus®)	
	Level L1 (LOT# 1706185F)	Level L2 (LOT# 1706186D)	Level L1 (LOT# Y 525)	Level L2 (LOT# Y 525)
Ascorbic Acid	n.a.	n.a.	n.a.	n.a.
Bilirubin	Negative	1+ – 3+	Negative	1+ – 3+
Blood	Negative	Trace – 3+	Negative	Trace – 3+
Glucose	Negative	100 – ≥2000 mg/dl	Negative	100 – ≥1000 mg/dl Trace – 3+
Ketones	Negative	5 – 160 mg/dl	Negative	5 – ≥160 mg/dl Trace – 4+
Leucocytes	Negative	Trace – 3+	Negative	Trace – 3+
Nitrite	Negative	Positive	Negative	Positive
pH	5.0 – 6.0	6.5 – 8.5	5.0 – 6.5	7.0 – ≥9.0
Protein	Negative	Trace – ≥2000 mg/dl Trace – 4+	Negative	Trace – ≥2000 mg/dl Trace – 4+
Specific Gravity	1.020 – 1.030	1.000 – 1.020	1.015 – ≥1.030	≤1.005 – 1.020
Urobilinogen	Normal	2 – 8 mg/dl	Normal	1 – ≥8 mg/dl

Siemens Multistix PRO® 10SL Urinalysis Reagent Strips				
Analyte	Visual		Instrumental (Siemens Clinitek Status® / Advantus®)	
	Level L1 (LOT# 1706185F)	Level L2 (LOT# 1706186D)	Level L1 (LOT# 1706185F)	Level L2 (LOT# 1706186D)
Blood	Negative	Trace – 3+	Negative – Trace	Trace – 3+ ≤5 – ca. 200 Ery/μl
Creatinine	10 – 200 mg/dl	100 – 300 mg/dl	10 – 200 mg/dl	100 – ≥300 mg/dl 8.8 – ≥26.5 mmol/l
Glucose	Negative	100 – ≥2000 mg/dl	Negative	100 – ≥2000 mg/dl 5.5 – ≥111 mmol/l
Ketones	Negative	5 – 160 mg/dl	Negative	5 – ≥160 mg/dl 0.5 – ≥16.0 mmol/l Trace – 4+
Leucocytes	Negative	Trace – 3+	Negative	Trace – 3+ 15 – 500 Leu/μl
Nitrite	Negative	Positive	Negative	Positive
pH	5.0 – 6.5	6.5 – 8.5	5.0 – 6.5	6.5 – ≥9.0
Protein, High	Negative	30 – 2000 mg/dl 1+ – 4+	n.a.	n.a.
Protein, Low	Negative	15 mg/dl	n.a.	n.a.
Protein	n.a.	n.a.	Negative	15 – ≥2000 mg/dl Trace – 4+ ≤0.5 – 20.0 g/l
Protein:Creatinine	n.a.	n.a.	Normal	Abnormal
Specific Gravity	1.020 – 1.030	1.000 – 1.020	1.020 – ≥1.030	1.000 – 1.020

Siemens Clinitek® Microalbumin Urinalysis Reagent Strips				
Analyte	Visual		Instrumental (Siemens Clinitek Status® / Advantus®)	
	Level L1 (LOT# 1706185F)	Level L2 (LOT# 1706186D)	Level L1 (LOT# Y 525)	Level L2 (LOT# Y 525)
Microalbumin	n.a.	n.a.	0 – 10 mg/l	30 – 150 mg/l
Creatinine	n.a.	n.a.	10 – 200 mg/dl	100 – 300 mg/dl



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Roche ChemStrip® Urinalysis Reagent Strips				
Analyte	Visual (10SG, 10UA, 10MD)		Instrumental (Roche Urisys 1100® / 2400®)	
	Level L1 (LOT# 1706185F)	Level L2 (LOT# 1706186D)	Level L1 (LOT# 1706185F)	Level L2 (LOT# 1706186D)
Bilirubin	Negative	1+ – 3+	Negative	1 – 6 mg/dl 1+ – 3+ 17 – 100 µmol/l
Blood	Negative	Trace – 250 Ery/µl	Negative	5 – 250 Ery/µl Trace – 4+
Glucose	Normal	50 – 1000 mg/dl	Normal	50 – ≥1000 mg/dl Trace – 4+ 2.8 – ≥56 mmol/l
Ketones	Negative	1+ – 3+	Negative	5 – 150 mg/dl Trace – 3+ 0.5 – ≥15.0 mmol/l
Leucocytes	Negative	Trace – 2+	Negative	25 – 500 Leu/µl Trace – 2+
Nitrite	Negative	Positive	Negative	Positive
pH	5.0 – 6.0	7.0 – 9.0	5.0 – 6.5	7.0 – 9.0
Protein	Negative	Trace – 500 mg/dl Trace – 3+	Negative	15 – 500 mg/dl Trace – 3+ 0.15 – 5.0 g/l
Specific Gravity	1.015 – 1.030	1.000 – 1.020	1.015 – 1.030	1.000 – 1.020
Urobilinogen	Normal	1 – 12 mg/dl	Normal	1 – ≥8 mg/dl 1+ – 4+ 16 – ≥128 µmol/l

Roche Combur <sup>10</sup> Test® Urinalysis Reagent Strips				
Analyte	Visual		Instrumental (Roche Urisys 1100® with Combur <sup>10</sup> Test® UX)	
	Level L1 (LOT# 1706185F)	Level L2 (LOT# 1706186D)	Level L1 (LOT# 1706185F)	Level L2 (LOT# 1706186D)
Bilirubin	Negative	1+ – 3+	Negative	1 – 6 mg/dl 1+ – 3+ 17 – 100 µmol/l
Blood	Negative	5 – 250 Ery/µl 1+ – 4+	Negative	Trace – 250 Ery/µl Trace – 4+
Glucose	Normal	50 – 1000 mg/dl 1+ – 4+	Normal	50 – ≥1000 mg/dl Trace – 4+ 2.8 – ≥56 mmol/l
Ketones	Negative	10 – 150 mg/dl 1+ – 3+	Negative	15 – 150 mg/dl 1+ – 3+ 0.5 – ≥15.0 mmol/l
Leucocytes	Negative	10 – 500 Leu/µl 1+ – 3+	Negative	25 – 500 Leu/µl Trace – 3+
Nitrite	Negative	Positive	Negative	Positive
pH	5.0 – 6.0	7.0 – 9.0	5.0 – 6.5	7.0 – 9.0
Protein	Negative	30 – 500 mg/dl 1+ – 3+	Negative	Trace – 500 mg/dl Trace – 3+ 0.15 – 5.0 g/l
Specific Gravity	1.015 – 1.030	1.000 – 1.020	1.015 – 1.030	1.000 – 1.020
Urobilinogen	Normal	1 – 12 mg/dl 1+ – 4+	Normal	1 – ≥12 mg/dl 1+ – 4+ 16 – ≥128 µmol/l

Qualitative Tests		
Test	Level L1 (LOT# Y 525)	Level L2 (LOT# Y 525)
hCG*	Negative	Positive

\* Lateral Flow Test

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Glossary (GB)	Glossar (DE)	Glossaire (F)	Glossario (I)	Glosario (ES)	Glossário (PT)	Ordlista (S)	Ordliste (N)
Level	Level	Niveau	Livello	Nivel	Nível	Nivå	Nivå
Ascorbic acid	Ascorbinsäure	Acide ascorbique	Acido ascorbico	Ácido ascórbico	Ácido ascórbico	Askorbinsyra	Askorbinsyre
Bilirubin	Bilirubin	Bilirubine	Bilirubina	Bilirrubina	Bilirrubina	Bilirubin	Bilirubin
Blood	Blut	Sang	Sangue	Sangre	Sangue	Blod	Blod
Creatinine	Kreatinin	Créatinine	Creatinina	Creatinina	Creatinina	Kreatinin	Kreatinin
Glucose	Glukose	Glucose	Glucosio	Glucosa	Glicose	Glukos	Glukose
Ketones	Ketone	Cétones	Chetoni	Cetonas	Cetonas	Ketoner	Ketoner
Leucocytes	Leukozyten	Leucocytes	Leucociti	Leucocitos	Leucócitos	Leukocyter	Leukocytter
Microalbumin	Mikroalbumin	Microalbumine	Microalbumina	Microalbúmina	Microalbumina	Mikroalbumin	Mikroalbumin
Nitrite	Nitrit	Nitrite	Nitriti	Nitrito	Nitrito	Nitrit	Nitritt
pH	pH	pH	pH	pH	pH	pH	pH
Protein	Protein	Protéine	Proteine	Proteína	Proteína	Protein	Protein
Specific Gravity	Spezifisches Gewicht	Gravité spécifique	Peso específico	Densidad relativa	Gravidade específica	Specifik vikt	Spesifikk vekt
Urobilinogen	Urobilinogen	Urobilinogène	Urobilinogeno	Urobilinógeno	Urobilinogénio	Urobilinogen	Urobilinogen
Normal	Normal	Normal	Normale	Normal	Normal	Normalt	Normalt
Negative	Negativ	Négatif	Negativo	Negativo	Negativo	Negativ	Negative
Positive	Positiv	Positif	Positivo	Positivo	Positivo	Positiv	Positiv
Visual	Visuell	Visuellement	Visivamente	Visualmente	Visualmente	Visuellt	Visuelt
Instrumental	Instrumentell	Instrumentalement	Strumentalmente	Instrumentalmente	Instrumentalmente	Instrumentellt	Instrumentelt
Qualitative	Qualitativ	Qualitatif	Qualitativo	Qualitativo	Qualitativo	Kvalitativ	Kvalitativ

Glossary (GB)	Ordliste (DK)	Sanasto (FIN)
Level	Niveau	Taso
Ascorbic acid	Askorbinsyre	Askorbiinihappo
Bilirubin	Bilirubin	Bilirubiini
Blood	Blod	Veri
Creatinine	Kreatinin	Kreatiini
Glucose	Glucose	Glukoosi
Ketones	Ketoner	Ketonit
Leucocytes	Leukocyter	Valkosolut
Microalbumin	Mikroalbumin	Microalbumin
Nitrite	Nitrit	Nitriitti
pH	pH	pH
Protein	Protein	Proteiini
Specific Gravity	Specifik vægt	Spesifinen paino
Urobilinogen	Urobilinogen	Urobilinoseenin
Normal	Normalt	Normaalisti
Negative	Negativ	Negatiivinen
Positive	Positiv	Positiivinen
Visual	Visuellt	Visuaalisesti
Instrumental	Instrumentellt	Välineellisesti
Qualitative	Kvalitativ	Laadullinen

Anmerkung: Grau hinterlegte Textpassagen wurden in der letzten Überarbeitung dieser Gebrauchsanweisung geändert.  
Note: Text passages with grey background were changed in the latest revision of this package insert.