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Specification

Cat. No.: 06334601001

Product: **cobas u pack**

Storage Conditions:

+ 2 °C – + 30 °C

Testing Procedures:

Analysis of Ingredients

Specification of ingredients:

The results are expressed in concentration values between lower and upper limit of the tolerances.

System Performance Testing

Native Urine and phosphate buffer solution spiked with defined analyte concentrations.

The reaction color is measured by the analytical system.

Specification for system performance:

The results are expressed in values (% remission or digital units) between lower and upper limit of the tolerances.

Part 1: Blood

3,3', 5,5'-tetramethylbenzidine	≥ 219	nmol/cm ²
2,5-dimethyl-2,5-dihydroperoxyhexane	≥ 1.67	μmol/cm ²

Performance on cobas u 601

Artificial Urine	69.4 – 79.4	%Rem
10 Ery/μL	49.5 – 69.5	%Rem
150 Ery/μL	≤ 27	%Rem
0-native Urine	68.5 – 78.5	%Rem

Part 2: Bilirubin

2,6-dichlorbenzen-diazonium-tetrafluoroborate	66.1 – 136.1	nmol/cm ²
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Performance on cobas u 601

Artificial Urine	66.1 – 76.1	%Rem
1 mg/dL	47.9 – 57.9	%Rem
6 mg/dL	≤ 32.5	%Rem
0-native Urine	62.3 – 72.3	%Rem

Part 3: Urobilinogen

4-methoxybenzene-diazonium-tetrafluoroborate 305.6 – 472.2 nmol/cm²

Performance on cobas u 601

Artificial Urine	65.6 – 78.1	%Rem
1 mg/dL	57.9 – 67.9	%Rem
8 mg/dL	33.3 – 43.3	%Rem
0-native Urine	59.9 – 74.9	%Rem

Part 4: Ketone

Sodium nitroprusside ≥ 528 nmol/cm²

Performance on cobas u 601

Artificial Urine	49.3 – 64.3	%Rem
10 mg/dL	28.2 – 48.2	%Rem
150 mg/dL	≤ 13.8	%Rem
0-native Urine	46.1 – 61.1	%Rem

Part 5: Glucose

3,3', 5,5'-tetramethylbenzidine	415.0 – 650.0	nmol/cm ²
Glucoseoxidase (GOD)	≥ 6.0	TMB-U/cm ²
Peroxidase (POD)	≥ 35.0	TMB-U/cm ²

Performance on cobas u 601

Artificial Urine	70.4 – 80.4	%Rem
50 mg/dL	36.2 – 51.2	%Rem
300 mg/dL	≤ 27.1	%Rem
0-native Urine	69.6 – 79.6	%Rem

Part 6: Proteine

3',3'',5',5''-tetrachlorophenol- 3,4,5,6-tetrabromosulfophthalein	17.2 – 23.1	nmol/cm ²
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Performance on cobas u 601

Artificial Urine	62.7 – 75.2	%Rem
30 mg/dL	42.0 – 54.5	%Rem
150 mg/dL	20.7 – 33.2	%Rem
0-native Urine	60.8 – 73.3	%Rem

Part 7: Nitrite

Sulfanilamide	169.5 – 254.0	nmol/cm ²
3-hydroxy-1,2,3,4-tetrahydro-7,8-benzoquinoline	168 – 250	nmol/cm ²

Performance on cobas u 601

Artificial Urine	61.4 – 73.9	%Rem
0,1 mg/dL	50.8 – 60.8	%Rem
0-native Urine	61.6 – 71.6	%Rem

Part 8: Leucocytes

Indoxylcarbonic acid ester	47.0 – 65.0	nmol/cm ²
methoxymorpholinobenzene diazonium salt	17.2 – 69.4	nmol/cm ²

Performance on cobas u 601

Artificial Urine	63.5 – 73.5	%Rem
1,4 U/dL	51.3 – 66.3	%Rem
56,0 U/dL	≤ 28.1	%Rem
0-native Urine	61.2 – 71.2	%Rem

Part 9: Compensation

No ingredients

Performance on cobas u 601

Artificial Urine green LED	61.4 – 76.4	%Rem
Artificial Urine true green LED	65.7 – 80.7	%Rem
Artificial Urine blue LED	65.1 – 75.1	%Rem
Artificial Urine orange LED	66.9 – 76.9	%Rem
0-native Urine green LED	60.7 – 75.7	%Rem

Part 10: pH

Bromothymol blue	22.2 – 35.0	nmol/cm ²
methyl red	4.1 – 6.2	nmol/cm ²
phenolphthalein	21.2 – 36.3	nmol/cm ²

Performance on cobas u 601

Artificial Urine green LED	36.1 – 51.2	%Rem
pH 9,0 orange LED	≤ 10.4	%Rem

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