	Acetaminophen 505 / 2K99-20	Acetaminophen 506 / 03R11-20
Note: Unless otherwise indicated, data was collected on a Roche/Hitachi® 717 analyzer. For information specific to ARCHITECT c-Systems analysis, refer to the cSystems Acetaminophen Assay Parameters.		
510 (K) Number:	K042330	K081938
Manufactured by	Sekisui Diagnostics	Sekisui Diagnostics
Test Principle:	The enzyme, acyl amidohydrolase, cleaves the amide bond of the acetaminophen molecule, leaving p-aminophenol and acetate. The p-aminophenol is reacted with 8-hydroxyquinoline-5 sulfonic acid in the presence of manganese ions to form a colored compound, 5-(4-iminophenol)-8-quinolone. The increased absorbance at 615 nm due to the formation of 5-(4-iminophenol)-8-quinolone is directly proportional to the concentration of acetaminophen in the sample.	The enzyme, acyl amidohydrolase, cleaves the amide bond of the acetaminophen molecule, leaving p-aminophenol and acetate. The p-aminophenol is reacted with 2,5-dimethylphenol in the presence of manganese ions to form a colored compound, 4-(4-iminophenol)-2,5-dimethylcyclohexadiene-1-one. The increased absorbance at 605 (660 [4]) nm due to the formation of 4-(4-iminophenol)-2,5-dimethylcyclohexadiene-1-one is directly proportional to the concentration of acetaminophen in the sample.
Methodology	Enzymatic/Colorimetric	Enzymatic/Colorimetric
Sample Types:	Fresh, clear, unhemolyzed serum or lithium heparinized plasma. EDTA is not suitable for use.	Fresh, clear, unhemolysed serum or lithium heparinized plasma. EDTA is not suitable for use.
Fill Requirements:	N/A	Use a minimum volume of 20ml of R2 reagent at a time, using only 20 ml wedges. When adding additional reagent to the analyzer use a new wedge. [4]
On Board Stability	12 days (288 hours) [4]	8 days (192 hours) [4]
Calibration Stability	12 days (288 hours)[4]	24 hours [4]
Precision	**Within-run**: ≤ 1.0% **Total Precision**: ≤ 1.8%	**Within-run**: ≤ 1.5% **Total Precision**: ≤ 2.9%
Accuracy	**Serum[1]** Slope: 1.01 Intercept: -3.80 µg/mL (-25.2 µmol/L) Correlation Coefficient: 0.9976 **Plasma[2]** Slope: 1.01 Intercept -0.1 µg/mL (-0.7 µmol/L) Correlation Coefficient: 0.9996	**Serum[1]** Slope: 1.064 Intercept: 1.1 µg/mL (7.0 µmol/L) Correlation Coefficient: 0.9998 **Plasma[3]** Slope: 0.999 Intercept -0.3 µg/mL (-2.2 µmol/L) Correlation Coefficient: 0.9999
Linearity	3-380 µg/mL (20 – 2500 µmol/L)	0.6 – 377.5 ug/mL (4 – 2500 µmol/L)
No Significant Interference to levels indicated (See insert/IFU for complete listing)	▪ N-Acetylcysteine: 200 mg/L ▪ Hemoglobin: 200 mg/dL (31 µmol/L) ▪ Bilirubin: 24 mg/dL (410 µmol/L) ▪ Intralipid: 400 mg/dL (1200 mg/dL Simulated Triglyceride)	▪ N-Acetylcysteine: 1500 mg/L (9.2 mmol/L) ▪ Hemoglobin: 200 mg/dL (31 µmol/L) ▪ Conjugated Bilirubin: 2 mg/dL (23.7 µmol/L) ▪ Unconjugated Bilirubin: 2 mg/dL (34.2 µmol/L) ▪ Ascorbic Acid: 3000 µg/dL (170 µmol/L) ▪ Intralipid: 200 mg/dL (600 mg/dL Simulated Triglyceride)

[1] SERUM: The performance of this method (y) was compared with the performance with a similar acetaminophen method (x) on a Roche/Hitachi® 717 analyzer.

[2] PLASMA: The performance of this method with plasma (y) was compared to the performance of this method with serum (x) on an Advia® 1650 analyzer.

[3] PLASMA: The performance of this method with plasma (y) was compared to the performance of this method with serum (x) on a Roche/Hitachi® 717 analyzer

[4] Testing completed on Architect c8000 system

Revised 2018-Feb-06
Edits highlighted.