



Certificate of Quality

Product Name: Methadone Metabolite Enzyme Immunoassay

Product Size: c pack kit 200 tests (21.25 mL R₁, 9.53 mL R₂)

Reference Number: 09067671190

Description: The Methadone Metabolite Immunoassay is a homogeneous enzyme immunoassay intended for use in the qualitative and semi-quantitative determination of methadone metabolite in human urine.

Lot Number: 66297501

Spike-In Date: September 14, 2022

Expiration Date: October 31, 2023

QC/QA results: cobas c 503 100 ng/mL cutoff

Semi-Quantitative control recovery results: ng/mL

	(min)	ng/mL	(max)
Negative Control (75 ng/mL):	68	<u>76</u>	83
Positive Control (125 ng/mL):	113	<u>131</u>	138

Qualitative control cross-over results: % agreement

	(min)	% Agreement	(max)
Negative Control (75 ng/mL):	95	<u>100%</u>	100
Positive Control (125 ng/mL):	95	<u>100%</u>	100



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QC/QA results: cobas c 503 300 ng/mL cutoff

Semi-Quantitative control recovery results: ng/mL

	(min)	ng/mL	(max)
Negative Control (225 ng/mL):	203	<u>233</u>	248
Positive Control (375 ng/mL):	338	<u>383</u>	413

Qualitative control cross-over results: % agreement

	(min)	% Agreement	(max)
Negative Control (225 ng/mL):	95	<u>100%</u>	100
Positive Control (375 ng/mL):	95	<u>100%</u>	100

Storage/Preparation: The reagents are ready to use. No reagent preparation is required. All assay components should be stored at 2-8°C when not in use.

Wayne Chih 

QC/QA: Wayne Chih & Jayson Gonzalez

Date: November 23, 2022