EXAMPLE CUALIA MV

CUALIA.IO EXAMPLE MV

Created with

CUALIA.IO

Category	Detail
Organization Name	Cualia.io
Lab Name	Cualia Labs
Department Name	Chemistry
Evaluator	Calvin Lang
Lab Contact	Lisa Owens

Table of Contents

Summary

Introduction

Analyzer	Cualia Chemi 56
Display Name	CC56
Identifier	SRM9376212024
Website	https://cualia.io
Manufacturer	Cualia Labs
Methodology(s)	Electrochemiluminescence Immunoassay, and Spectrophotometric

The Cualia Chemi 56 (CC56) is a state-of-the-art clinical chemistry and immunoassay analyzer designed to deliver high throughput and exceptional reliability. Offering a fully automated solution, it efficiently processes a broad range of tests, including routine chemistry, immunoassays, and specialized assays. Its architecture supports rapid turnaround times and consistent results, helping laboratories improve workflow and productivity. Equipped with intuitive software and user-friendly interfaces, the CC56 simplifies operation while maintaining strict quality control standards. This advanced system is trusted worldwide for accuracy, making it an ideal choice for clinical labs seeking performance and versatility in one compact platform.

Objective

Name	Abbreviation	Analyte	Type	Experiments
Triglyceride	TAG	Triglyceride	Quantitative	5 / 5 (100%)
Cholesterol Total	Tot Chol.	Cholesterol Total	Quantitative	4 / 4 (100%)
Glucose	GLUC	Glucose	Quantitative	4 / 4 (100%)
Creatinine	Crea	Creatinine	Quantitative	4 / 4 (100%)
Anti-Human Immunodeficiency virus	Anti-HIV	Anti-Human Immunodeficiency virus	Qualitative	4 / 4 (100%)
Anti Hepatitis B	AntiHB	Anti Hepatitis B	Qualitative	4 / 4 (100%)
Syphillis	SYPH	Syphillis	Qualitative	4 / 4 (100%)

Studies Performed

Experiment	Test Progress
Precision	7 / 7 (100%)
Limit of Blank	4 / 4 (100%)
Limit of Detection	3 / 3 (100%)
Limit of Quantification	1 / 1 (100%)
Method Comparison	6 / 6 (100%)
Linearity	1 / 1 (100%)
Trueness	7 / 7 (100%)

Materials

	Label	Source	Lot Number	Expiration	Comments
1	Performance Verifier	SM Manufacturer	J871266	May 10 2026	
2	Performance Verifier 03	SM Manufacturer	Z832819	May 10 2026	
3	Calibrator Kit 1	CL IO	HHH1239	Dec 08 2025	

Quantitative Tests

TAG - Triglyceride

Quantitative Test	TAG - Triglyceride
Analyte Name	Triglyceride
Units	mg/l
Validation Status	No
Range	110 - 200
LoB Reference Value	0.05
Description	

Experiment Name	**Status**
Precision	Passed
Limit of Blank	Passed
Limit of Quantification	Passed
Method Comparison	
Linearity	Passed
Reference Interval	
Trueness	Passed
Carryover	
Interference	

Tot Chol. - Cholesterol Total

Quantitative Test	Tot Chol. - Cholesterol Total
Analyte Name	Cholesterol Total
Units	mg/l
Validation Status	No
Range	-
LoB Reference Value	0.05
Description	

Experiment Name	**Status**

Precision	Passed
Limit of Blank	Passed
Limit of Quantification	
Method Comparison	Passed
Linearity	
Reference Interval	
Trueness	Passed
Carryover	
Interference	

GLUC - Glucose

Quantitative Test	GLUC - Glucose
Analyte Name	Glucose
Units	mg/L
Validation Status	No
Range	-
LoB Reference Value	0.05
Description	

Experiment Name	**Status**
Precision	Passed
Limit of Blank	Passed
Limit of Quantification	
Method Comparison	Passed
Linearity	
Reference Interval	
Trueness	Passed
Carryover	
Interference	

Crea - Creatinine

Quantitative Test	Crea - Creatinine
Analyte Name	Creatinine
Units	mg/dL
Validation Status	Yes
Range	1.2 - 346.5
LoB Reference Value	0.05
Description	Serum creatinine and urinary creatinine excretion is a function of lean body mass in normal persons and shows little or no response to dietary changes. The serum creatinine concentration is higher in men than in women. Since urinary creatinine is excreted mainly by glomerular filtration, with only small amounts due to tubular secretion, serum creatinine and a 24-hour urine creatinine excretion can be used to estimate the glomerular filtration rate.

Experiment Name	**Status**
Precision	Passed
Limit of Blank	Passed
Limit of Quantification	
Method Comparison	Passed
Linearity	
Reference Interval	
Trueness	Passed
Carryover	
Interference	

Qualitative Tests

Anti-HIV - Anti-Human Immunodeficiency virus

Qualitative Test	Anti-HIV - Anti-Human Immunodeficiency virus
Analyte Name	Anti-Human Immunodeficiency virus
Units	
Validation Status	No
Results	Neg | Pos
Minimum Detectable Concentration	1
Description	

Experiment Name	Status
Precision	Passed
Limit of Detection	Passed
Method Comparison	Passed
Trueness	Passed

AntiHB - Anti Hepatitis B

Qualitative Test	AntiHB - Anti Hepatitis B
Analyte Name	Anti Hepatitis B
Units	
Validation Status	No
Results	Neg | Pos
Minimum Detectable Concentration	1
Description	

Experiment Name	Status
Precision	Passed
Limit of Detection	Passed
Method Comparison	Passed
Trueness	Passed

SYPH - Syphillis

Qualitative Test	SYPH - Syphillis
Analyte Name	Syphillis
Units	
Validation Status	No
Results	Neg | Pos
Minimum Detectable Concentration	1
Description	

Experiment Name	**Status**
Precision	Passed
Limit of Detection	Passed
Method Comparison	Passed
Trueness	Passed

Experiments

Precision

Precision refers to the consistency of test results when the same qualitative test is repeated under identical conditions. It measures the reproducibility of categorical outcomes, such as positive or negative results, ensuring the method produces the same results consistently across different runs and operators. High qualitative precision is essential for the reliability of diagnostic tests.

Test	Acceptance Criteria	Results	Experiments
TAG Quantitative	Samples: 355Total Allowable Error (TEa) Random Error Allowance (REa) (50% TEa at 7.5%)	Agreement: 100%	Passed
Tot Chol. Quantitative	Samples: 355Total Allowable Error (TEa) Random Error Allowance	Agreement: 100%	Passed
GLUC Quantitative	Samples: 355Total Allowable Error (TEa) Random Error Allowance (REa) (50% TEa at 5%)	Agreement: 98.67%	Passed
Crea Quantitative	Samples: 355Total Allowable Error (TEa) Random Error Allowance (REa) (50% TEa at 0.25 or 5%)	Agreement: 98.67%	Passed
Anti-HIV Qualitative	Samples: 355 Min. Between Day Agreement (%): 95%	Agreement: 100%	Passed
AntiHB Qualitative	Samples: 355 Min. Between Day Agreement (%): 95%	Agreement: 97.33%	Passed
SYPH Qualitative	Samples: 355 Min. Between Day Agreement (%): 95%	Agreement: 98.67%	Passed

Limit of Blank

The Limit of Blank (LoB) is the highest measurement result that is likely to be observed for a blank sample (a sample

without the analyte of interest). It represents the threshold above which an analyte can be confidently detected, distinguishing between the absence of the analyte and its presence at very low levels. The LoB is determined by measuring the responses of multiple blank samples.

Test	Acceptance Criteria	Results	Experiments
TAG Quantitative	Days: 550.05	Limit of Blank value: 0	Passed
Tot Chol. Quantitative	Days: 550.05	Limit of Blank value: 0	Passed
GLUC Quantitative	Days: 550.05	Limit of Blank value: 0.05	Passed
Crea Quantitative	Days: 550.05	Limit of Blank value: 0	Passed

Limit of Detection

The Qualitative Limit of Detection (LoD) refers to the lowest concentration of an analyte that can be reliably distinguished from the absence of that analyte (a blank sample) but not necessarily quantified. It is a critical parameter in method validation, ensuring that the method can detect even the smallest amounts of the substance of interest.

Limit of Quantification

The Limit of Quantitation (LoQ) is the lowest concentration of an analyte that can be quantitatively detected with acceptable precision and accuracy using a specific analytical method. It ensures that measurements at this level are reliable and reproducible. The LoQ is higher than the Limit of Detection (LoD) because it requires not just detection but also quantifiable precision.

Method Comparison

Method Comparison is one of the primary MV experiments. It involves comparing your instrument's*actual*results with those of a true reference instrument. This verifies that the new method produces results that are in agreement.

Test	Acceptance Criteria	Results	Experiments
Tot Chol. Quantitative	Min. Samples: 20Total Allowable Error Min. Agreement (%): 95%	Samples: 20100%	Passed
GLUC Quantitative	Min. Samples: 20Total Allowable Error (TEa) (NYS - 10%) Min. Agreement (%): 95%	Samples: 2095%	Passed
Crea Quantitative	Min. Samples: 20Total Allowable Error (TEa) (RCPA - 0.5 or RCPA - 10%) Min. Agreement (%): 95%	Samples: 20100%	Passed
Anti-HIV Qualitative	Min. Samples: 20 Min. Agreement (%): 95%	Samples: 2095%	Passed
AntiHB Qualitative	Min. Samples: 20 Min. Agreement (%): 95%	Samples: 2095%	Passed
SYPH Qualitative	Min. Samples: 20 Min. Agreement (%): 95%	Samples: 2095%	Passed

Linearity

Linearity in MV refers to the ability of an analytical method to produce results that are directly proportional to the concentration of the analyte within a given range. It ensures that the method can accurately measure varying concentrations of the analyte and that the response (e.g., signal intensity) increases consistently with the analyte concentration. Linearity is typically assessed by analyzing multiple standards of known concentrations.

Test	Acceptance Criteria	Results	Experiments
TAG Quantitative	Levels: 53 Min. Coefficient (R): 0.95	r:	Passed

Trueness

Trueness is one of the primary MV experiments. It involves comparing your instrument's*actual*results with those an EQA

qualified sample. The mechanism is similar to Method Comparison, but compares*actual*results with highly validated results for comparison. Few samples may be used for comparison due to stringent sample requirements.

Test	Acceptance Criteria	Results	Experiments
TAG Quantitative	Min. Samples: 5Total Allowable Error (TEa) (CLIA 2024 - 15%) Min. Agreement (%): 95%	Samples: 5100%	Passed
Tot Chol. Quantitative	Min. Samples: 5Total Allowable Error Min. Agreement (%): 95%	Samples: 5100%	Passed
GLUC Quantitative	Min. Samples: 5Total Allowable Error (TEa) (NYS - 10%) Min. Agreement (%): 95%	Samples: 5100%	Passed
Crea Quantitative	Min. Samples: 5Total Allowable Error (TEa) (RCPA - 0.5 or RCPA - 10%) Min. Agreement (%): 95%	Samples: 5100%	Passed
Anti-HIV Qualitative	Min. Samples: 5 Min. Agreement (%): 95%	Samples: 5100%	Passed
AntiHB Qualitative	Min. Samples: 5 Min. Agreement (%): 95%	Samples: 5100%	Passed
SYPH Qualitative	Min. Samples: 5 Min. Agreement (%): 95%	Samples: 5100%	Passed

Conclusions

Conclusions and Final Remarks

Name	Abbreviation	Analyte	Type	Experiments
Triglyceride	TAG	Triglyceride	Quantitative	5 / 5 (100%)
Cholesterol Total	Tot Chol.	Cholesterol Total	Quantitative	4 / 4 (100%)
Glucose	GLUC	Glucose	Quantitative	4 / 4 (100%)
Creatinine	Crea	Creatinine	Quantitative	4 / 4 (100%)
Anti-Human Immunodeficiency virus	Anti-HIV	Anti-Human Immunodeficiency virus	Qualitative	4 / 4 (100%)
Anti Hepatitis B	AntiHB	Anti Hepatitis B	Qualitative	4 / 4 (100%)
Syphillis	SYPH	Syphillis	Qualitative	4 / 4 (100%)

Based on the results of the experiments, the Performance Evaluation / Method Verification of the Cualia Chemi 56 was shown to be up to performance standards and ready for test result reporting.