

Performance Qualifications for Erba Chem5X

1. PRECISION CHECK:

(After performing Glucose calibration, prepare Glucose reaction solution of one concentration of around 5ml and aspirate this reaction 500ul 5 times and note down readings and calculate CV. CV should be below 3%)

SR. NO.	GLU
Precision-1	100.1
Precision-2	102
Precision-3	102.6
Precision-4	102
Precision-5	100
MEAN	101.34
SD	1.07629
CV%	0.87

2. KINETIC, END-POINT MODE CHECK :

(Process the Biochemistry check with reagents and controls as per the kit insert literatures.)

TEST	LEVEL 1		LEVEL 2	
	Normal Control		High Cotrol	
	First run	Second run	First run	Second run
SGPT	38.90	30.06	123.8	137.9
TRIG	86.30	86.11	144.5	144.1
UAC	4.48	4.55	11.58	12.0
BID	0.68	0.69	1.67	1.77
CHOL	119.0	118	154.6	168.1
CRET	1.31	1.62	3.48	3.52

Conclusion:

The result for all the performance tests carried out for the instrument meets the acceptance criteria. Hence the instrument is qualified for the performance.

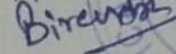
Protocol performed By:-

TBM, Technical Services Department

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Name : Mr. Birendra Yadav

Designation: Application Specialist

Signature : 

Date : 24/02/22

CUSTOMER DETAIL

Customer Detail

Name : Dr. Shital Madam

Designation: Pathologist

Signature :

Date :