



IQURE DIAGNOSTICS

PRECISION & ACCURACY

ACCESS2

		TotT3	TotT4	TSH3	HCG	VitB12
	1	216.60	12.30	5.04	22.23	461.00
	2	213.87	12.44	4.93	22.42	483.00
	3	213.06	12.35	5.10	21.61	456.00
	4	211.00	12.59	5.00	22.05	461.00
	5	217.33	12.78	5.06	21.83	463.00
	6	215.61	12.22	5.09	21.99	457.00
	7	215.62	12.54	5.17	22.48	455.00
	8	212.63	12.47	5.05	22.32	458.00
	9	219.89	12.29	5.10	22.01	444.00
	10	213.84	12.30	5.20	21.94	464.00
MEAN		214.9	12.4	5.1	22.1	460.2
SD		2.60	0.17	0.08	0.27	9.81
CV %		1.21	1.38	1.54	1.24	2.13
BC LIMITS%		<10%	<10%	<7.0%	<10%	<12%

Beckman Coulter India Pvt. Ltd.

Registered Office: Unit Nos.TF-B-07(A) to 15, Third Floor, B Wing, Art Guild House, Phoenix Market City, LBS Road, Kuria (West), Mumbai - 400 070. Tel: +91 22 6838 5000 Fax: +91 22 6838 5060
 CIN : U33119MH2005PTC157177 www.beckmancoulter.com

Annexure 3.
Access-2 Immunoassay System Performance Evaluation.

Following Procedure was Carried out as part of the Performance Qualification:-

1. Calibration of Assay.

Assays calibrated and checked –: T3, T4, TSH3, VITB12 and BHCG.
Checked and found all calibrations are valid Curve.

2. Internal Quality Control Performance.

Bio-Rad Immunoassays Control
Checked and found Controls are within the acceptable limits.

3. Precision Study

Run Precision for T3, T4, TSH3, VITB12 and BHCG
assays of 10 replicates was carried out, CV % obtained
Are within the acceptable limit for the assay.
See print outs attached.

4. Carryover Check

Performed the Carryover study in Access2 as per BCI protocol
See printout attached

5. ACCESS-2 Methodology & Range

See print outs attached

Company Name	BECKMAN COULTER INDIA PVT. LTD.	Page 1 of 6
Equipment Name	IMMUNOASSAY Analyser (Access-2)	Serial No: 571402
Performance Qualification (PQ)		

Beckman Coulter India Pvt. Ltd.

QC Chart and Data Screen

You use this screen to:

- View QC data and Levey-Jennings charts
- Edit the date range of the quality control
- Copy QC data to a disk
- Print reports

To get to this screen from the Main Menu, select Quality Control F4 to display the Quality Control screen, select the quality control you want to view, then select Review Chart and Data F2.

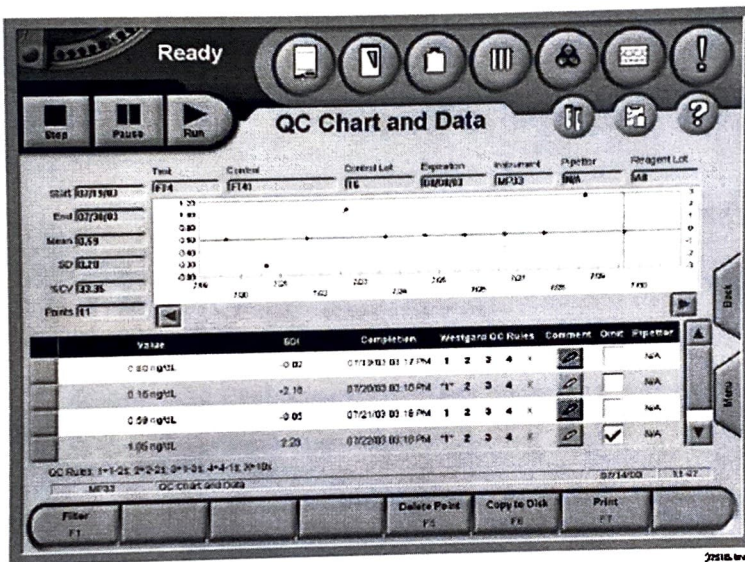


Figure 7-6 QC Chart and Data Screen

Test	(Field) Displays the test name.
Control	(Field) Displays the quality control name.

Table 7-7 QC Chart and Data Screen Descriptions

Company Name	BECKMAN COULTER INDIA PVT. LTD.	Page 4 of 6
Equipment Name	IMMUNOASSAY Analyser (Access-2)	Serial No: 571402
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Selected test Results Report

Access2, Access Immunoassay System

S/N 571402, Version 3.6.0

Filter: Prog - Sorted by Sample ID Than by Test Name

<u>Patient ID</u>	<u>Sample ID</u>	<u>Rack</u>	<u>Test Name</u>	<u>Results</u>	<u>Comp.Time</u>	<u>Flags</u>	<u>Pipettor</u>
	PRECISION	400	VitB12	461.00	pg/ml	4/1/19 11:18 AM	1
	PRECISION	400	VitB12(2)	483.00	pg/ml	4/1/19 11:19 AM	1
	PRECISION	400	VitB12(3)	456.00	pg/ml	4/1/19 11:19 AM	1
	PRECISION	400	VitB12(4)	461.00	pg/ml	4/1/19 11:32 AM	1
	PRECISION	400	VitB12(5)	463.00	pg/ml	4/1/19 11:32 AM	1
	PRECISION	400	VitB12(6)	457.00	pg/ml	4/1/19 11:34 AM	1
	PRECISION	400	VitB12(7)	455.00	pg/ml	4/1/19 11:35 AM	1
	PRECISION	400	VitB12(8)	458.00	pg/ml	4/1/19 11:35 AM	1
	PRECISION	400	VitB12(9)	444.00	pg/ml	4/1/19 11:36 AM	1
	PRECISION	400	VitB12(10)	464.00	pg/ml	4/1/19 11:36 AM	1

Technologist _____

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<u>Patient ID</u>	<u>Sample ID</u>	<u>Rack</u>	<u>Test Name</u>	<u>Results</u>	<u>Comp.Time</u>	<u>Flags</u>	<u>Pipettor</u>
	PRECISION	400	HCG5	22.23 mIU/mL	4/1/19 11:13 AM		1
	PRECISION	400	HCG5(2)	22.42 mIU/mL	4/1/19 11:13 AM		1
	PRECISION	400	HCG5(3)	21.61 mIU/mL	4/1/19 11:14 AM		1
	PRECISION	400	HCG5(4)	22.05 mIU/mL	4/1/19 11:16 AM		1
	PRECISION	400	HCG5(5)	21.83 mIU/mL	4/1/19 11:17 AM		1
	PRECISION	400	HCG5(6)	21.99 mIU/mL	4/1/19 11:17 AM		1
	PRECISION	400	HCG5(7)	22.48 mIU/mL	4/1/19 11:20 AM		1
	PRECISION	400	HCG5(8)	22.32 mIU/mL	4/1/19 11:20 AM		1
	PRECISION	400	HCG5(9)	22.01 mIU/mL	4/1/19 11:21 AM		1
	PRECISION	400	HCG5(10)	21.94 mIU/mL	4/1/19 11:23 AM		1

Technologist _____

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Filter: Prog - Sorted by Sample ID Than by Test Name

<u>Patient ID</u>	<u>Sample ID</u>	<u>Rack</u>	<u>Test Name</u>	<u>Results</u>	<u>Comp.Time</u>	<u>Flags</u>	<u>Pipettor</u>
	PRECISION	400	TotT3	216.60	ng/dl	4/1/19 11:43 AM	1
	PRECISION	400	TotT3(2)	213.87	ng/dl	4/1/19 11:43 AM	1
	PRECISION	400	TotT3(3)	213.06	ng/dl	4/1/19 11:45 AM	1
	PRECISION	400	TotT3(4)	211.00	ng/dl	4/1/19 11:46 AM	1
	PRECISION	400	TotT3(5)	217.33	ng/dl	4/1/19 11:47 AM	1
	PRECISION	400	TotT3(6)	215.61	ng/dl	4/1/19 11:48 AM	1
	PRECISION	400	TotT3(7)	215.62	ng/dl	4/1/19 11:50 AM	1
	PRECISION	400	TotT3(8)	212.63	ng/dl	4/1/19 11:50 AM	1
	PRECISION	400	TotT3(9)	219.89	ng/dl	4/1/19 11:52 AM	1
	PRECISION	400	TotT3(10)	213.84	ng/dl	4/1/19 11:53 AM	1

Technologist _____

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Filter: Prog - Sorted by Sample ID Than by Test Name

<u>Patient ID</u>	<u>Sample ID</u>	<u>Rack</u>	<u>Test Name</u>	<u>Results</u>	<u>Comp.Time</u>	<u>Flags</u>	<u>Pipettor</u>
	PRECISION	400	TotT4	12.30 ug/dl	4/1/19 11:55 AM		1
	PRECISION	400	TotT4(2)	12.44 ug/dl	4/1/19 11:56 AM		1
	PRECISION	400	TotT4(3)	12.35 ug/dl	4/1/19 11:56 AM		1
	PRECISION	400	TotT4(4)	12.59 ug/dl	4/1/19 11:57 AM		1
	PRECISION	400	TotT4(5)	12.78 ug/dl	4/1/19 11:58 AM		1
	PRECISION	400	TotT4(6)	12.22 ug/dl	4/1/19 11:58 AM		1
	PRECISION	400	TotT4(7)	12.54 ug/dl	4/1/19 12.04 PM		1
	PRECISION	400	TotT4(8)	12.47 ug/dl	4/1/19 12.05 PM		1
	PRECISION	400	TotT4(9)	12.29 ug/dl	4/1/19 12.05 PM		1
	PRECISION	400	TotT4(10)	12.30 ug/dl	4/1/19 12.06 PM		1

Technologist _____

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Filter: Prog - Sorted by Sample ID Than by Test Name

<u>Patient ID</u>	<u>Sample ID</u>	<u>Rack</u>	<u>Test Name</u>	<u>Results</u>	<u>Comp.Time</u>	<u>Flags</u>	<u>Pipettor</u>
	PRECISION	400	TSH3	5.04	uIU/ml	4/1/19 11:18 AM	1
	PRECISION	400	TSH3(2)	4.93	uIU/ml	4/1/19 11:19 AM	1
	PRECISION	400	TSH3(3)	5.10	uIU/ml	4/1/19 11:19 AM	1
	PRECISION	400	TSH3(4)	5.00	uIU/ml	4/1/19 11:32 AM	1
	PRECISION	400	TSH3(5)	5.06	uIU/ml	4/1/19 11:32 AM	1
	PRECISION	400	TSH3(6)	5.09	uIU/ml	4/1/19 11:34 AM	1
	PRECISION	400	TSH3(7)	5.17	uIU/ml	4/1/19 11:35 AM	1
	PRECISION	400	TSH3(8)	5.05	uIU/ml	4/1/19 11:35 AM	1
	PRECISION	400	TSH3(9)	5.10	uIU/ml	4/1/19 11:36 AM	1
	PRECISION	400	TSH3(10)	5.20	uIU/ml	4/1/19 11:36 AM	1

Technologist _____