



OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA NANO

AGAPPE DIAGNOSTICS LTD.

ADL/BO/SER/0021/21-22

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT Agappe Hills, Pattimattom (PO), Dist, Ernakulam, Kerala - 683 562, India. Tel: + 91 484 286 7000 | Email: agappe@agappe.in

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APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

SURGING INNOVATIO: SERVING MAN MIND

Both POOJA DIAGNOSTICS, BANGALORE and AGAPPE DIAGNOSTICS LTD. are jointly responsible for the installation of MISPA NANO with serial number XJ 2100579 at "POOJA DIAGNOSTICS, NO:8, ABOVE CANARA BANK, 80 FEET ROAD, CHANDRA LAYOUT, BANGALORE" as per the attached OPERATIONAL QUALIFICATION protocol.



Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	:	DANI DAVIS V	Signature	e:
Designation	:	Engineer - Customer Service	Date	: 19/03/2012
Company	:	AGAPPE DIAGNOSTICS LTD.		

Validation Team from POOJA DIAGNOSTICS, BANGALORE

Name	:	Signature	e :
Designation	:	Date	:
Department	:		

Customer Authorizations:

Name :

Title	: OPERATIONAL QUALIFICATION	Signature	:
Site	:	Date	:

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SURGING INNOV SERVING MEANINE

II. INSTRUCTIONS

An authorized AGAPPE DIAGNOSTICS LTD representative will check and enter the specific data as outlined in the OPERATIONAL QUALIFICATION. Each result will be noted and dated.

2. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the OQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

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III. SCOPE

This Operational Qualification protocol will be performed on the **MISPA NANO** at **POOJA DIAGNOSTICS, BANGALORE**. This Installation protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

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IV. OPERATIONAL QUALIFICATION



Verified Date : 19/03/2012

nstrument Identification

SURGING INNOVATION Model Name

: MISPA NANO

2. Serial Number : XJ 2100579

B. Following is a list of tests to be performed and verified:

ĺ	Test No.	Test Name	Test purpose	Verified By and date
	01	Start up	To make the equipment ready for operation	DANI DAVIS V
	02	Daily maintenance	To clean appropriate modules	DANI DAVIS V
	03	Calibration	To calibrate the system	DANI DAVIS V
	04	QC check	To confirm that the system is calibrated and working within specifications	DANI DAVIS V
	05	Reproducibility check	To check the precision [CV %] after calibration	DANI DAVIS V
	06	Sample programming and Analysis	To run the samples	DANI DAVIS V
_	07	Shut down procedure	To shut down the system	DANI DAVIS V

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Summary:

Instrument checks functioning of different parts of the instrument automatically. If there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Wait for the instrument to get ready after initialization .
- Check the room temperature and switch on the Air Conditioner
- Check the UPS. .
- Switch on the MISPA NANO by pressing the main switch, then switch on the computer • and then the system power
- Double click the analyzer icon to initialize the system software
- Input the password and do as prompted, the system menu pops up if start up is finished •
- If not, initialize by again after solving the error displayed .
- Follow instructions provided for the error message

Acceptance criteria: System to display READY status

PARAMETER PASS FAIL

Parameter values for verification: "READY" on Status Area

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CRISSRATING Test 02: Daily Maintenance

urpose: To clean appropriate modules so as per the daily maintenance protocol

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Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Empty waste container	DANI DAVIS V	19/03/2012
02	Check Wash solutions	DANI DAVIS V	19/03/2012
03	Check system water	DANI DAVIS V	19/03/2012
04	Check Reagents	DANI DAVIS V	19/03/2012
05	Clean Reagent Block	DANI DAVIS V	19/03/2012
06	Clean out side area	DANI DAVIS V	19/03/2012
07	Load supplies and remove outdated and empty reagents	DANI DAVIS V	19/03/2012
08	Check main menu screen	DANI DAVIS V	19/03/2012
09	Perform Quality Control	DANI DAVIS V	19/03/2012

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER FAIL PASS

Parameter values for verification: System found "Ready" after daily maintenance

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Purpose: To calibrate the system

Procedure:

S No	Activity	Done By	Date
01	Preparation of the cal material	DANI DAVIS V	19/03/2012
02	Performing Calibration with calibration programming screen	DANI DAVIS V	19/03/2012

Acceptance criteria: Calibration data shows concordance OD values in triplicate measurement

PARAMETER	PASS	FAIL
Parameter values for ver	rification	: No error message in the printout

Test 04: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	DANI DAVIS V	19/03/2012
02	Creating QC file	DANI DAVIS V	19/03/2012
03	QC sample programming and analysis	DANI DAVIS V	19/03/2012

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER PAS	SS
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Parameter values for verification: QC values within ± 2SD

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FAIL

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Test 05: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	DANI DAVIS V	19/03/2012
02	Running triplicates	DANI DAVIS V	19/03/2012

Acceptance criteria: Results CV within specified limits

PARAMETER PASS FAIL

Parameter values for verification: CV% within the limits

Test 06: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	DANI DAVIS V	19/03/2012
02	Programming samples	DANI DAVIS V	19/03/2012
03	Aspirating the samples	DANI DAVIS V	19/03/2012
04	Viewing samples in process	DANI DAVIS V	19/03/2012
05	Review results: Monitoring results	DANI DAVIS V	19/03/2012

Acceptance criteria: Samples Analysis without any error

PARAMETER PASS FAIL

Parameter values for verification: Sample analysis without any error

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Surging and Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	DANI DAVIS V	19/03/2012
02	Following the on screen instructions	DANI DAVIS V	19/03/2012
03	Switch off the instrument when prompted	DANI DAVIS V	19/03/2012

Acceptance criteria: Shut down without any error

PARAMETER PASS FAIL

Parameter values for verification: Shut down without any error

V. OPERATIONAL PROCEDURE

Certificate of Training

1. <u>Technician Training</u>

This certifies that the technicians have received basic user training in the following

categories for the system described in this Operational Qualification.

	S No.	Training program	Initials	Date
	1	Instrument Setup		
	2	System Operation		
	3	Basic trouble shooting and Maintenance		

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SURGING INMOVATION 2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

Į	S No.	Operators	Department	Initials	Date
1					
4					

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VI. COMMENTS

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VII. SYSTEM CERTIFICATION

AGAPPE Study data has determined that the system described in this document either meets all criteria outline in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Performance Qualification.

DIAGNOS

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Report Perfor	med By: AGAPPE DIAGNOSTICS LTD. Represent	tative	ALORE-
Name	: DANI DAVIS V		
Designation	: Engineer - Customer Service	Signature	:
Company	: AGAPPE DIAGNOSTICS LTD.	Date	:
Customer Aut	thorizations: POOJA DIAGNOSTICS, BANGALOR	E	
Name	:		
Designation	:	Signature	:
Title	: OPERATIONAL QUALIFICATION	Date	:

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I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both POOJA DIAGNOSTICS, BANGALORE and AGAPPE DIAGNOSTICS LTD. are jointly responsible for the installation of MISPA NANO with serial number XJ 2100579 at "POOJA DIAGNOSTICS , NO:8, ABOVE CANARA BANK, 80 FEET ROAD, CHANDRA LAYOUT, BANGALORE" as per the attached Installation Qualification protocol.



AGAPPG

Protocol Performed By : Representative of AGAPPE DIAGNOSTICS LTD.

Name	:	DANI DAVIS V	Signature	2:
Title	:	Engineer - Customer Service	Date	:19/03/2012
Company	:	AGAPPE DIAGNOSTICS LTD.		

Validation Team from POOJA DIAGNOSTICS, BANGALORE

Name	:	Signatur	e:
Designation	:	Date	:
Department	:		

Customer Authorizations:

N	am	е	:
	•••••	-	•

Title : INSTALLATION QUALIFICATION

Site :

Signature	:
0	

Date :

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 [EN ISO 13485:2016 CERTIFIED COMPANY]CIN: U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT Agappe Hills, Pattimattom (PO), Dist. Ernakulam, Kerala - 683 562, India. Tel: + 91 484 286 7000 | Email: agappe@agappe.in

MUMBAI [REGISTERED OFFICE] 401 & 402, 4th Floor, Jaisingh Business Centre, 119, Sahar Road, Parsiwada, Andheri (East), Mumbai - 400 099, India. Tel: +91 22 4300 8000 | Email: mumbaioffice@agappe.in

EOUIPMENT PLANT X/588-CB, Block No. 32, KINFRA Small Industrial Park, Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

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- II. INSTRUCTIONS
 - An authorized AGAPPE DIAGNOSTICS LTD. representative will check and enter the specific data as outlined in the Installation Qualification. Each result will be noted and dated.
 - The concerned employees of POOJA DIAGNOSTICS, BANGALORE will verify each result and sign in each page. The member of the validation team will carry this out.
 - 3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the IQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

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CELSSRATING

SCOPE 111.

surging new This Installation Qualification protocol will be performed on the MISPA NANO at

POOJA DIAGNOSTICS, BANGALORE. This Installation protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

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IV.

INSTALLATION QUALIFICATION



Verified Date :

An Instrument Identification

SERVING MAND

- 1. Model Name : MISPA NANO
- 2. Serial Number : XJ 2100579

B. Following is a list of accessories /consumables verified:

	S No.	Component	Present (Yes/No)	Verified By	Comments
	01	Analyzer Main unit	Yes	DANI DAVIS V	
	02	Computer	Yes	DANI DAVIS V	
	03	Printer	Yes	DANI DAVIS V	
	04	RS232 Connector cable	Yes	DANI DAVIS V	
	05	Power cord	Yes	DANI DAVIS V	
	06	Waste can	Yes	DANI DAVIS V	
2	07	Water can	Yes	DANI DAVIS V	
	08	Water connector tube	Yes	DANI DAVIS V	
	09	Waste connector tube	Yes	DANI DAVIS V	
	10	Water pre filter	Yes	DANI DAVIS V	
	11	Probe assembly	Yes	DANI DAVIS V	
	12	Mixer assembly	Yes	DANI DAVIS V	
	13	Reagent tray	Yes	DANI DAVIS V	
	14	Cuvette blocks	Yes	DANI DAVIS V	
	15	Reagent bottles	Yes	DANI DAVIS V	

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Purpose: To make sure that the instrument is received with all the major

components necessary for operation

	S No.	Component	(Yes/No)	Verified By	Comments
	1	Major components and accessories are present	Yes	DANI DAVIS V	
	2	There is no physical damage to the components	Yes	DANI DAVIS V	
	3	Ambient temperature is available	Yes	DANI DAVIS V	
	4	Instrument is installed in the table leveled properly	Yes	DANI DAVIS V	
	5	Power supply is correct	Yes	DANI DAVIS V	
	6	Electric connections are tight, weatherproof & earthed	Yes	DANI DAVIS V	
ĺ	7	Analyzer unit installed as per the manufacturers recommendations	Yes	DANI DAVIS V	

Summary:

The information is recorded against each data and the deviations if any is justified /

explained properly.

Acceptance criteria:

PARAMETER

PASS

FAIL

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AGAPPE



AGAPPE

SURGING D. Instrument Installation

Date of Installation : 19/03/2012

Installed by : DANI DAVIS V

Ĩ	S No.	Parameter	Done by	Comments
	01	Installation of the main unit	DANI DAVIS V	
	02	Installation of the computer system	DANI DAVIS V	
	03	Installation of the printer	DANI DAVIS V	
	04	Connecting the waste tubing	DANI DAVIS V	
	05	Connecting the system water tubing	DANI DAVIS V	
	06	Installing the reagent tray	DANI DAVIS V	
2	07	Installation of the probe	DANI DAVIS V	
	08	Installation of the mixer	DANI DAVIS V	
	09	Installing the cuvettes	DANI DAVIS V	

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER PASS FAIL

Parameter values for verification: System found "Ready" after daily maintenance

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CELSSRATING



E. <u>Cell Blank</u>

urpose: To check the cuvette blank OD at different wavelength

SURGING INNOVATION SERVING MATProcedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	DANI DAVIS V	19/03/2012
02	340 nm	DANI DAVIS V	19/03/2012
03	405 nm	DANI DAVIS V	19/03/2012
04	450 nm	DANI DAVIS V	19/03/2012
05	510 nm	DANI DAVIS V	19/03/2012
06	546 nm	DANI DAVIS V	19/03/2012
07	578 nm	DANI DAVIS V	19/03/2012
08	630 nm	DANI DAVIS V	19/03/2012
09	670 nm	DANI DAVIS V	19/03/2012

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER PASS FAIL

Parameter values for verification: No Error Messages

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CELSBRATING Priming



urpose: To check the internal tubing's and flow of liquids

SURGING INNOVATION SERVICE MANY INTO

4	S No	Activity	Done By	Date	
	01	Do wash using the maintenance screen	DANI DAVIS V	19/03/2012	

Acceptance criteria:

- No error message or air bubbles in the internal tubing's •
- All the dilutor working well without air bubbles / leakage •

PARAMETER PASS FAIL

Parameter values for verification: No Error Messages

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V. COMMENTS

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SURGING VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Operational Qualification.



:

:

Report Performed By: AGAPPE DIAGNOSTICS LTD. Representative

Designation	: Engineer - Customer Service	Signature

: AGAPPE DIAGNOSTICS LTD. Company Date

Customer Authorizations: POOJA DIAGNOSTICS, BANGALORE

Name	:		
Designation	:	Signature	:
Title	: INSTALLATION QUALIFICATION	Date	:

AGAPPE DIAGNOSTICS LTD. 150 9001:2015 [EN ISO 13485:2016 CERTIFIED COMPANY] CIN : U24239MH1998PLC115413

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PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA NANO

AGAPPE DIAGNOSTICS LTD.

ADL/BO/SER/0031/21-22

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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	IV	Performance Qualification	6
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SURGING T. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both POOJA DIAGNOSTICS, BANGALORE and AGAPPE DIAGNOSTICS LTD. are jointly responsible for the installation of MISPA NANO with serial number XJ 2100579 at "POOJA DIAGNOSTICS, NO:8, ABOVE CANARA BANK, 80 FEET ROAD, CHANDRA LAYOUT, BANGALORE" as per the attached PERFORMANCE Qualification protocol.



AGAPPE

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

	Name	:	DANI DAVIS V	Signature	:
	Designation	:	Engineer - Customer Service	Date	:19/03/2012
1	Company	:	AGAPPE DIAGNOSTICS LTD.		

Validation Team from POOJA DIAGNOSTICS, BANGALORE

Name	:	Signature	:
Designation	:	Date	:
Department	:		

Customer Authorizations:

Name :

 Title
 : PERFORMANCE QUALIFICATION
 Signature

 Site
 :
 Date

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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CRESSRATING

SURGING INNOVATI SERVING MARKER

II. INSTRUCTIONS

An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.

- The concerned employees of POOJA DIAGNOSTICS, BANGALORE will verify each result and sign in each page. The member of the validation team will carry this out.
- 3. All deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the PQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION.

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AGAPPE





III. <u>SCOPE</u>

This Performance Qualification protocol will be performed on the **MISPA NANO** at **POOJA DIAGNOSTICS, BANGALORE.** This Performance protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

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IV. PERFORMANCE QUALIFICATION

A. Instrument Identification

Verified Date : 19/03/2012

AGAPPE

- 1. Model Name : MISPA NANO
- 2. Serial Number : XJ 2100579

B. Following is a list of tests to be performed and verified:

1	Test No.	Test Name	Test purpose	Verified By and date
	01	Start up	To make the equipment ready for operation	DANI DAVIS V
-	02	Daily maintenance	To clean appropriate modules	DANI DAVIS V
0	03	Cell blank	To check the cuvettes	DANI DAVIS V
	04	Priming	To check the tubing's , and flow	DANI DAVIS V
N	05	Auto gain	To check the cuvette and photometry system	DANI DAVIS V
t,	06	Calibration	To calibrate the system	DANI DAVIS V
	07	QC check	To confirm that the system and reagents are acceptable and working within specifications	DANI DAVIS V
	08	Reproducibility check	To check the precision [CV %]	DANI DAVIS V
1	09	Sample programming and Analysis	To run the samples	DANI DAVIS V
	10	Shut down procedure	To shut down the system	DANI DAVIS V

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Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Wait for the instrument to get ready after initialization .
- Check the room temperature and switch on the Air Conditioner
- Check the UPS. .
- Switch on the MISPA NANO by pressing the main switch, then switch on the computer • and then the system power
- Double click the analyzer icon to initialize the system software .
- Input the password and do as prompted, the system menu pops up if start up is • finished
- If not, initialize by again after solving the error displayed •
- Follow instructions provided for the error message

Acceptance criteria: System to display READY status

PARAMETER PASS FAIL

Parameter values for verification: "READY" on Status Area

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Purpose: To clean appropriate modules so as per the daily maintenance protocol

Method:

Refer detailed procedure for Daily Maintenance

	S No.	Activity	Done by	Date
	01	Empty waste container	DANI DAVIS V	19/03/2012
	02	Check Wash solutions	DANI DAVIS V	19/03/2012
	03	Check system water	DANI DAVIS V	19/03/2012
	04	Check Reagents	DANI DAVIS V	19/03/2012
	05	Clean Reagent Block	DANI DAVIS V	19/03/2012
	06	Clean out side area	DANI DAVIS V	19/03/2012
l	07	Load supplies and remove outdated and empty reagents	DANI DAVIS V	19/03/2012
	08	Check main menu screen	DANI DAVIS V	19/03/2012
	09	Perform Quality Control	DANI DAVIS V	19/03/2012

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER PASS FAIL

Parameter values for verification: System found "Ready" after daily maintenance

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AGAPPG





Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
	Checking the Cell blank	DANI DAVIS V	19/03/2012
	340 nm	DANI DAVIS V	19/03/2012
	405 nm	DANI DAVIS V	19/03/2012
	450 nm	DANI DAVIS V	19/03/2012
01	510 nm	DANI DAVIS V	19/03/2012
	546 nm	DANI DAVIS V	19/03/2012
	578 nm	DANI DAVIS V	19/03/2012
1	630 nm	DANI DAVIS V	19/03/2012
	670 nm	DANI DAVIS V	19/03/2012

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER

PASS

FAIL

Parameter values for verification: No Error Messages

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Purpose: To check the internal tubing's and flow of liquids

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	DANI DAVIS V	19/03/2012

Acceptance criteria:

- No error message or air bubbles in the internal tubing's
- All the dilutor working well without air bubbles / leakage

PARAMETER PASS FAIL

Parameter values for verification: No Error Messages

Test 05: Auto gain

Purpose: To Check the photometry system

Procedure:

S No.	Activity	Done By	Date
01	Performing the filter OD checking	DANI DAVIS V	19/03/2012

Acceptance criteria: Data shows OD values in the acceptable range

PARAMETER PASS FAIL

Parameter values for verification : No error message

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CELSSRATING

Test 06: Calibration of the system

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Furpose: To calibrate the system

SURGING INNOVATION SERVING MAIProcedure:

S No.	Activity	Done By	Date
01	Preparation of the Calibration material *	DANI DAVIS V	19/03/2012
02	Performing Calibration with calibration programming screen	DANI DAVIS V	19/03/2012

*Traceability of the calibrator used is attached

Acceptance criteria: Calibration data shows concordance OD values in triplicate measurement

PARAMETERPASSFAILParameter values for verification: No error message in the printout

Test 07: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	DANI DAVIS V	19/03/2012
02	Creating QC file	DANI DAVIS V	19/03/2012
03	QC sample programming and analysis	DANI DAVIS V	19/03/2012

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER

PASS

FAIL

Parameter values for verification: QC values within ± 2SD

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CELSBRATING

Test 08: Reproducibility Check

SURCPurpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	DANI DAVIS V	19/03/2012
02	Running triplicates	DANI DAVIS V	19/03/2012

Acceptance criteria: Results CV within specified limits

PARAMETER FAIL PASS

Parameter values for verification: CV% within the limits

Test 09: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	DANI DAVIS V	19/03/2012
02	Programming samples	DANI DAVIS V	19/03/2012
03	Aspirating the samples	DANI DAVIS V	19/03/2012
04	Viewing samples in process	DANI DAVIS V	19/03/2012
05	Review results: Monitoring results	DANI DAVIS V	19/03/2012

Acceptance criteria: Samples Analysis without any error

PARAMETER PASS FAIL

Parameter values for verification: Sample analysis without any error

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SRRVING MAJ Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	DANI DAVIS V	19/03/2012
02	Following the on screen instructions	DANI DAVIS V	19/03/2012
03	Switch off the instrument when prompted	DANI DAVIS V	19/03/2012

Acceptance criteria: Shut down without any error

PARAMETER PASS FAIL

Parameter values for verification: Shut down without any error

OPERATIONAL PROCEDURE

Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1.	Instrument Setup		
2.	System Operation		
3.	Basic trouble shooting and Maintenance		

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11

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
	S No.	S No. Operators	S No. Operators Department	S No. Operators Department Initials

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AGNO

Study data has determined that the system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: AGAPPE DIAGNOSTICS LTD. Representative				
	Name	: DANI DAVIS V		
	Designation	: Engineer - Customer Service	Signature	:
	Company	: AGAPPE DIAGNOSTICS LTD.	Date	:
	Customer Aut	horizations: POOJA DIAGNOSTICS, BANGALOR	E	
	Name	:		
	Designation	:	Signature	:
	Title	: PERFORMANCE QUALIFICATION	Date	:

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PRODUCT	: EM - 180	
SERIAL NO.	: B-180038	
PROV. NO.	: 09/B06	
ASW VERSION	: 2014.01.02	2
ESW VERSION	: 2014.0.12	
VOLTAGE SUPPLY	: 220V	
DATE	: 31/07/2014	4
CONCLUSION	: PASS	· ·
CHECKED BY	: Divya	ing.
REVIEWED BY	:	
(Prod. Head)	L	1
VERIFIED & APPROVED BY	: FIBhavo	mel
(QA Head)	93	

Revised date :02.06.14

Prov. No 09/806

LAI BHYSICAL CHECKING				
[A] THISICAL CHE				
1) 50 POSITION SAMPLE AND REAGENT TRAY (SRGT)	Fitting :	ок	Movement :	ок
2) 2 EXTERNAL DILUENT POSITIONS	Fitting :	ок		
3) REACTION TRAY (RCT)	Centering :	ОК	Movement :	ОК
4) REAGENT/SAMPLE PIPETTOR	Centering :	ОК	Movement :	OK Liquid Flow : OK
5) STIRRER	Centering :	ОК	Movement :	OK
6) REACTION TRAY COVER	Fitting :	ОК]	
7) SAMPLE & REAGENT TRAY COVER	Fitting :	ок]	
8) DOME COVER	Fitting :	OK]	
9) GAS SPRINGS	Closing :	ОК	Movement :	ок
10) INDICATOR LAMPS			_	
a) ANALYZER SWITCH :		ОК		
b) LED ON ARM AND PANEL :		ок		

Revised date :02.06.14

2 of 7 (Pg 7 is optional for ISE)

[B] PRE-BIOCHEMISTRY CHECK

1) TEMPERATURE

SERVICE MENU

RUN TEST

	Observed	
RCT:	37] °C
RGT:	11] °C
RCT:	37] °C
RGT:	11] °c

Acceptance 36.5 to 37.5°C 04 to 12 °C 36.5 to 37.5°C 04 to 12 °C

Prov. No.

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09/B06

2) AUTO SPAN SET

Acceptance criterial for Gain at all wavelength: 380 to 600

	2 TO THE R	GAIN	
WAVELENGTH -	1	2	3
340	406	406	406
405	449	449	.449
505	444	444	444
546	422	422	422
578	476	476	476
600	548	548	548
660	506	506	506
700	455	455	• 455

3) SENSORS :

1. DEIONISED WATER

2. WASTE

	OK	
[OK	1

Revised date :02.06.14

....Prov. No. 09/B06

[C] OTHER FUNCTIONAL CHECKS

		the second s	
1) PRIME MODE	ОК	9) MULTIPOINT CALIBRATION	ОК
2) ROTOR CHECK	ОК	10) EMERGENCY MODE	ок
3) REAGENT LEVEL SCAN	ОК	11) DILUTION MODE	OK
4) REACTION CURVE	ОК	12) 2 REAGENT CHEMISTRY	ОК
5) RECALCULATION	ОК	13) QC MODE	OK
6) RESULT DATA REPRINT	ОК	14) AUTOSTART-UP AND SHUT-DOWN [MAINTAINANCE	ок
7) PATIENT REPORT PRINT	ОК	15) HIBERNATE MODE	OK
8) MAINTENANCE - WASH	OK .		
D DEAD VOLUME CHECK			
SAMPLE	Observed	Acceptance	
SAMPLE CUP (2ML) in µl	100	50µl TO 150 µl	
SAMPLE TUBE(5 - 7 ML)in µl	350	250µI ТО 450 µI	
REAGENT			
REAGENT : 50ML BOTTLE in ml	2	1.5 ml TO 2.5 ml	
REAGENT : 20ML BOTTLEin ml	1.5	1.0 ml TO 2.0 ml	
REAGENT : 5 ML ADAPTORin µl	455	350 µl TO 650 µl	

QCX18-401/Issue-02

Revised date :02.06.14

4 of 7 (Pg 7 is optional for ISE)

.. Prov. No. 09/806

E) OPTIONAL CONFIGURATION STATUS

1] IS MACHINE WITH ISE MODULE? (YES / NO)

Centering:

	NA	
1.	9	

NA

NO

Electrodes:

2] IS MACHINE WITH	BARCODE? (YES / NO)	

BARCODE SCAN

YES OK

9

-

Revised date :02.06.14

F1] WITHIN RUN PRECISION CHECK

		<u> </u>		MULTICA		91305C		ERBA NOR	M: 20	071415		ERBA PAT	'H: 20	071416
ITEM		ALB		СНО	T	GGT		GLU	1	COT	-			
RGT Lot No). 10	031304	10-	41305U	10	21403	10	1120411		GPT		PRO	L	IREA
Expiry Date	0	3/2016	- 10	0/2014	0	2/2016		12015	100	513010	10	21305	10	31402
UNIT	-	g/dl	1	ng/dl		10/1		n2015		/2015	- 08	/2015	11	/2015
SPECIMEN	NORM	PATH	NORM	PATH	NORM	PATH	NOPM					g/dl	п	ıg/dl
1	4.64	5.46	175	213	47.3	03.8	104.7	PATH	NORM	PATH	NORM	PATH	NORM	PATH
2	4.63	5.42	174	214	46.1	05.4	104.7	2/2.8	56.4	133.8	6.73	8.23	44.50	176.3
3	4.65	- 5.51	176	212	47.0	07.2	104.0	275	50.9	127.6	6.63	8.33	44.60	174.1
4	4.60	5.49	176	217	43.9	02.4	103.6	271.7	47.2	128.6	6.68	8.23	44.00	175.10
5	4.66	5.45	174	216	42.6	80.0	104.2	275.4	49.2	126.4	6.63	8.30	44.40	174.10
6	4.69	5.45	178	218	44.6	09.8	103.7	277.9	48.4	125.9	6.68	8.25	44.40	177.00
7	4.64	5.45	175	216	44.0	90.8	104.0	274.7	50.4	123.7	6.71	8.32	44.70	178.80
8	4.61	5.47	178	211	44.5	92.7.	104.2	273	49.2	126.9	6.68	8.22	44.40	176.70
9	4.70	5.50	177	211	44.0	91.2	104.7	276.1	49.7	127.9	6.63	8.35	44 10	174.10
10	4.65	5.48	178	215	43.2	97.8	103.9	271.4	48.9	126.4	6.66	8.33	43.50	175.70
11	4.69	5.47	175	211	44.4	91.6	104.0	276.6	49.9	124.4	6.67	8.32	43.60	175.00
12	4.63	5.54	175	214	40.5	90.9	103.9	275.3	48.2	128.1	6.66	8.22	44.40	173.00
13	4.62	5.43	172	210	44.0	94.7	104.4	277.2	49.2	126.4	6.61	8 30	43.40	174.90
14	4.63	5.43	172	215	40.4	92.3	103.6	278.8	48.9	127.9	6.68	8 30	43.40	173.70
15	4.64	5.44	174	213	40.1	91,4	103.4	279.4	49.9	130.1	6.60	8 30	43.00	170.90
16	4.61	5.48	173	213	40.8	95.6	103.6	278.5	48.7	125.9	6.69	8.27	43.80	176.60
17	4.67	5.53	176	210	40.8	91.6	102.0	280.7	50.7	125.6	6.65	8.20	43.60	173.70
18	4.60	5.39	173	212	45.7	94.5	102.3	275.3	45.2	128.1	6.68	0.29	44.70	173.00
19	4.65	5.44	173	210	41.6	91.4	102.7	. 279.3	49.9	128.1	6.69	0.27	44.20	175.00
20	4.62	5.35	175	211	44.4	91.4	102.0	276	48.9	127.4	6.70	8.28	43.00	172.00
Mean	4.64	5.46	174.05	213	45.5	91,1	102.4	274.5	52.6	130.4	0.70	8.24	43.60	176.00
SD	0.029	0.045	1 077	213.50	44.92	93.23	103.57	275.98	49.62	127 48	0.04	8.26	42.60	173.60
CV(%)	0.63	0.83	1.077	2.236	1.900	2.364	0.844	2.608	2.180	2 007	6.66	8.28	43.97	174.86
C.4		0.00	1.07	1.05	4.23	2.54	0.81	0.94	4 39	4.75	0.033	0.040	0.580	1.848
ceptance:	Erbanorm	< 3.00 %	Erbanorm	< 3.00 m					4.00	1.75	0.50	0.48	1.32	1.06
Note: •(Erbapath GGT L1 Poole	< 3.00 % ed Control 3 ;	Erbapath 1 (Erba Norm	< 3.00 % < 3.00 % & Erba Path	Erbanorm Erbapath	< 5.00 % < 5.00 %	Erbanorm Erbapath	< 3.00 % < 3.00 %	Erbanorm Erbapath	< 7.50.% < 5.00 %	Erbanorm Erbapath	< 3.00 %	Erbanorm	< 5.00 %

AGAPPE

SUNGING MARINERS 2. Operator Training

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URATING H

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
1.	SHIBN	BIDCHEM	ship	22-3-12
2.	3131	BIDCHEM	Tri	26-3-12

AGAPPE DIAGNOSTICS LTD. 150 9001:2015 [EN ISO 13485:2016 CERTIFIED COMPANY] (IN : U24239MH1998PLC115413

CORPORATE OFTIKE / PLACENT PLANT Apappie Hills, Partimation (PO), Dist. Ernakutam, Kerala - 683 562, India. Tel. • 91 484 286 7000 (Ernail agappe@agappe.in

MUMBAI (REGISTERED OFFICE) 4014 402, 4° Floor, Jasingh Business Centre, 119, Sahar Road, Patshada, Anthrei (Essi), Manisai - 400 099, India. Tel: -91 22 4300 8000 (Email: mambaioflice.stagappe.in EQUIPMENT PLANT X/588-CB, Block No. 32, K-NFRA Small Industrial Park Neilid, Cualun, Kerala, Judia - 686 721, Tet: +91 464 276 7477.

DELEN DEFICE DSM 540, 5[°] filoor, DCF Tower, Shivaji Marg, New Delid - 110 015, india Tel. +91 11 4558 6416 | Cincal: delinoffic eQegappe an KOLKATA OFFICE 436, Merlin Matria, Piot No 10, Block-ON, Sector V, Salt Lake City, Kolkata - 700 (1911 Tell +91 33 4003 04511 Email: Kolkattaoffice@agappe.in

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YOUR BEET PARTNER IN DIAGNOSTICS

1. 20 VIL. SYSTEM CERTIFICATION

AGAPPE F study data has determined that the system described in this document either meets all dutline in this Operational Qualification Protocol, or exceptional conditions have been seidentified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Performance Qualification.



Report Performed By: AGAPPE DIAGNOSTICS LTD. Representative

Name : DANI DAVIS V

Designation : Engineer - Customer Service

: AGAPPE DIAGNOSTICS LTD. Company

Signature Date

Signature

-03-2012

Customer Authorizations: POOJA DIAGNOSTICS, BANGALORE

Name	: DR. N. BHARAT
Designation	DIRECTOR
Title	: OPERATIONAL QUALIFICATION

19-3-12 Date :

POOJA DIAGNOSTICS & SUPER SPECIALITY CENT No.8. 80 faet Road, Chandra Lav. Randalore - 560 040

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 [EN ISO 13485:2016 CERTIFIED COMPANY] CIN : U24239MH1998PLC115413

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BANGALORE OFFICE BANGALORE OFFICE 5-6, II* Floor, Red Cross Bhavan, No.26 Race Course Road, Bangalore - 560 COL. Tel: +91 80 2228 8283 Curait: bangaloreoffice(Regappe.in

YOUR BEET PARTNER IN DIAGNOSTICS

DIRE HURSON STRATING B C SURGING TEMOTOGRAPHON SERVING MAN SOND

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
1.	SHIBU	BIOCHEM	spir	22/3/2012
2.	すっすり	BIDCHEM	ふう	26 3 2012

AGAPPE DIAGNOSTICS LTD. 150 9001:2015 1 EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT Agappe Hills, Pattimattom (PO), Dist. Ernakulam, Kevala - 683 562, India. Tel: + 91 484 286 7000 i Emai: agappe Jagappe in

MUMBAI (REGISTERED OFFICE) 401 & 402, 4° Floor, Jaisingh Business Centre, 119, Sahar Road, Parsiwada, Andheri (East), Mumbai - 400 099, India. Tel: +91 22 4300 8000 [Email: mumbaiofhoc@agappe.in

EQUIPMENT PLANT X/588-CB, Block No. 32, K:NFRA Small Industrial Park, Neilad, Cuchin, Kerala, Iudia - 686 721. Tel; +91 484 276 7472.

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KOLKATA OFFICE 406, Workin Matrico, Piot No-10, Block-DN, Sector V, 5al: Lake Caty, Rolkata - 200 091. rel: +91 33 4003 0451 Lemait: kolkattaoffice@agappe.in

AGAPPE

BANGALORE OFFICE 5-6, II⁺ Fixor, Red (ross Bhavan, Noz26 Race Course Road, Bangalore - 560 OOL 1-6: +91 60 2228 8288 Ensait: bangatureofficeQagappe.in

YOUR BEST PARTNER IN DIAGNOSTICS

VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Operational Qualification.

Report Performed By: AGAPPE DIAGNOSTICS LTD. Representative

Name : DANI DAVIS V

Designation : Engineer - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Customer Authorizations: POOJA DIAGNOSTICS, BANGALORE

Name	: DR. N. BHARAT.		Dower T
Designation	: DIRECTOR	Signature	: 02
Title	: INSTALLATION QUALIFICATION	Date	: 19-3-12

POOJA DIAGNOSTICS & SUPER SPECIALITY CEN No.8, 80 feet Road, Chandra L. Ranoalore - 560 040

AGAPPE DIAGNOSTICS LTD. 150 9001:2015 JEN ISO 13485:2016 CERTIFIED COMPANY J CIN ; U24239MH1998PLC115413 CORPORATE OFFICE / REAGENT PLANT

Agappe Hi Is, Paltimattom (PO), Dist. Ernakulam, Kerala - 683 562, India. Tel. + 91 484 286 7000 : Email: agappe2agappe3n

MUMBAI (REGISTERED OFFICE) 401 & 402, 4[®] Floor, Jasingh Business Centre, 119, Sahar Rical, Parshada, Andreiri (East), Mumbai - 400 099, India. Tel: +91 22 4300 8000 | Ensal¹: mumbaioffice:dagappe in

EQUIPMENT PLANT X/588-CB. Block No. 32, KINFRA Small Industrial Park, Neilad, Cochen, Kerala, India - 686 721, Tel. +91 464 276 7477.

DELHI OFFICE DSM 540, 5[°] filoar, DLF Tower, Shivaji Marg, New Delhi - 180 015, india, Tei: •91 II 4558 8416 | Cinati: defhioffiti eShagappe.in

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YOUR BEET PARTNER IN DIAGNOSTICS



19-03-2012



Signature

Date

:

:



VI. SYSTEM CERTIFICATION

TIERDUN

SURGING DEMOTING

TARATING T-

Study data has determined that the system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.



:

Report Performed By: AGAPPE DIAGNOSTICS LTD. Representative

Name : DANI DAVIS V

: Engineer - Customer Service Designation

: AGAPPE DIAGNOSTICS LTD. Company

Customer Authorizations: POOJA DIAGNOSTICS, BANGALORE

Name	:	JR. N. BHARAT	
Designation	:	DIRECTOR	S

: PERFORMANCE QUALIFICATION

Title

Signature :

:

Signature :

Date

19-3-12

19-03-2012

Date

POOJA DIAGNOSTICS & SUPER SPECIALITY CENTPR

No.8, 80 feet Road, Chandra Lav... Rangalore - 560 040

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 [EN ISO 13485:2016 CERTIFIED COMPANY] (IN : U24239MH1998PLC115413

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QC Data Summary

Control:	ERBA PATH	Start Date:	2/20/2022
		End Date:	2/20/2022

Test	Results	Units	Time	Control Range	Remarks/Flag
ALB	5.16	g/dL	2/20/2022 12:19:13 PM	4.5200-5.5200	
PROT	9.35	g/dL	2/20/2022 12:19:13 PM	8.1800-10.0200	
BILT	4.4	mg/dL	2/20/2022 12:19:13 PM	3.860-5.420	
URIC	12.9	mg/dL	2/20/2022 12:19:13 PM	10.980-13.420	
CREAT	3.34	mg/dL	2/20/2022 12:19:13 PM	2.8700-3.7900	
UREA	97.3	mg/dL	2/20/2022 12:19:13 PM	89.020-108.780	
TRIG	180	mg/dL	2/20/2022 12:19:13 PM	152.96-187.04	
CHOL	256	mg/dL	2/20/2022 12:19:13 PM	237.58-290.42	
GLU	262	mg/dL	2/20/2022 12:19:13 PM	221.40-270.60	

Current Calibration Results

Test	Rule	Status	Reagent Blank	SD	
К	R0	Α	B C	D	
GLU	Two-point Linear	Finished	-193.60937	231.5709402	
		40.91233	-79.51273		
CHOL	Two-point Linear	Finished	-432.44196	3.7799717	
		17.37502	2.81906		
TRIG	Two-point Linear	Finished	88.49910	9.775434	
		6.13497	5.61246		
HDL	Two-point Linear	Invalid			
HDL DIRECT	Two-point Linear	Finished	32.77264	6.6345329	
		37.63758	0.00000		
UREA	Two-point Linear	Finished	14336.13952	0	
		27.74510	0.00000		
CREAT	Two-point Linear	Finished	108.54232	0	
		185.59438	0.00000		
URIC	Two-point Linear	Finished	-556.52611	0	
		168.10180	-11.83529		
BILT	Two-point Linear	Finished	-38.85577	0	
		223.95965	0.00000		
BILD	Two-point Linear	Finished	-49.48962	0	
		311.14780	0.00000		
SGOT	Two-point Linear	Finished	11502.01254	0	
		5.51879	0.00000		
SGPT	Two-point Linear	Finished	13074.59406	0	
		6.01637	0.00000		
ALP	Two-point Linear	Finished	1865.54009	0	
		3.12634	0.00000		
PROT	Two-point Linear	Finished	270.16202	0	
		708.77882	4.90989		
ALB	Two-point Linear	Finished	351.04295	0	
		2158.87754	8.99386		
CALC	Two-point Linear	Finished	2136.63768	0	
		281.32682	-87.03658		
PHOS	Two-point Linear	Finished	2884.92180	0	
		1105.47791	1150.48072		
AMYL	Two-point Linear	Finished	-305.26967	0	
		3.92239	0.00000		
CKNAC	Two-point Linear	Invalid			

CKMB

Current Calibration Results

Test	Rule	Status		Reagent Blank	SD
К	R0	A	В	C	D
ASO	Two-point Linear	Invalid			
ENZ.CRET	Two-point Linear	Finished		-18.77931	0.2336081
		30.24816	0.00000		
CRP	Spline	Invalid		6445.54746	
RA	Two-point Linear	Finished		8850.02256	0
		23.82343	0.00000		
HBA1C	Spline	Finished		5058.77864	0
	0.00000	207.21630	-49.62501	10.33854	
GHB	Exponential 5P	Invalid			
CRP 1	Two-point Linear	Finished		9859.33833	0
		98.04678	0.00000		
MICROALBUMIN	Two-point Linear	Finished		360.92843	0
		16.03385	0.00000		
MICROPROTEIN	Two-point Linear	Finished		597.76483	0
		2.41892	-4.32048		
GAMMA GT	Two-point Linear	Finished		5742.38158	0
		6.43192	0.00000		
Test47		Invalid			
LDH	Two-point Linear	Finished		15084.19759	0
		0.72778	0.00000		