

STAR HUMAN Sciences Pvt. Ltd.

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CERTIFICATE OF CALIBRATION

Naranyan Pathology & Biopsy Centre 117/22, Sarvodya Nagar (Opp J.L Rohtagi Eye Hospital Near Baba Bhothnath Ashram) Kanpur-208005

This is to certify that the Instrument Humastar 200 Blochemistry Analyzer bearing serial no. 21191146004 manufactured by HUMAN GERMANY is in full working and has been calibrated to the standard specifications for the period of 09th December 2021 to 8th December 2022

Date of calibration: 09-12-2021

This calibration certificate is valid up to 08-12-2022

For Star Human Sciences Pvt. Ltd.

(Authorized Signatory)

Technical Calibration Detail

HS200 S. no. 21191146004

ITEMS	value	Target range
Lamp		an governing o
mV @ 340 nm	1230	900-1500
Current mV	6.5	OK
Efficiency@340	69	54-130
Pump		
Pump 1-5 volume uL	In range	220-520
Pump 1-5 flow rate uL/Sec	ОК	550-850

Other mechanical parameters in OS are in range as per standard criteria.

Dated-09-Dec-2021

Service Engineer

For Star Human Sciences Pvt. Ltd.

Performance Qualification HumaStar 100, HumaStar 200, HumaStar 300SR and HumaStar 600

Revision list

Revision	Date	Description	Editor
1	2018/08/14	First revision	Silvia Fischer

Lab Name

Narayan Pathology And Biopsy Centre Add- 117/22 Sarvodaya Nagar Kanpur

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Introduction

With the Performance Qualification we assure that HumaStar 100/200/300SR/600 will work under real life conditions (in the lab of the customer) according Human specifications.

All assays the customer is supposed to use should be checked during this test. The PQ can be done during the end user training or ahead in the laboratory of the customer.

For each test calibration, QC (two levels) and precision should be measured and analysed to check if the results are in the specification of Human.

If non Human reagents are used, the Performance Qualification should be done with Human reagents according the IFU (using Human calibrator and QC material)



1. Special materials

- Wash additive (18971) All HumaStar Systems
- Special wash solution (18974) HS 100/200
- Special wash solution-2 (18974/2) HS 300SR
- Cuvette Clean (16663/20) HS 600
- 0.9% NaCl solution HS 100/200
- Diluent (16663/10) HS300SR/600

1.1. Customer using Human reagents

All reagents, calibrator and QC material which the customer has chosen for the routine.

1.2. Customer using non Human reagents

- AutoCal (Ref 13160)
- Serodos (Ref 13951)
- HumaTrol P (Ref 13512)
- GLUCOSE liquicolor reagent (Ref 10121 HS 100/200; Ref 10260300 HS 300SR/600)
- CALCIUM liquicolor reagent (Ref 10011 HS 100/200; Ref 10011300 HS 300SR/600)
- GOT (ASAT) IFCC mod. liquidUV (Ref 12211 HS 100/200; Ref 12021300 HS 300SR/600)

2. Accompanying documents

- A) User Manuals (last revision, please check Human web page)
- B) Application sheets (on the PC)
- C) Package inserts (in the kits)

3. Performance quality checks

Step	Check	Expected result	Result	Final remark
1	Maintenance (perform all user maintenance)	All maintenance tasks finish without an error	DONE	OKAY
1	Calibration	Calibration factors should be in the specified range	IN RANGE	DONE
2	Quality Control	Both QC samples should be in range given by Human	IN RANGE	DONE



Step	Check	Expected result	Result	Final remark
3	Precision (n= 20), a Qc sample can be used	The CV in % for each test should be in the specified range	In all text < cv=3.1%	OKAY

4. Documentation

Please document all results in an additional document (excel file).

5. Calculation of the CV

Evaluate the results as following:
$$mean = \sum_{i=1}^{10} sample i$$

$$SD = \sqrt{\frac{\sum_{i=1}^{10} (sample i - mean)^2}{9}}$$

$$CV\% = \frac{SD*100}{mean}$$
 Easy to calculate in an EXCEL sheet using the appropriate formulas. See also example below

6. Example for calculations in EXCEL

12	A	В	C	D
1		target	min.	max.
2	Serodos	8,33	7,41	9,24
3				
4	sample 1	8,4		
5	sample 2	8,3		
6	sample 3	8,5		
7	sample 4	8,0		
8	sample 5	8,2		
9	sample 6	8,2		
10	sample 7	8,4		
11	sample 8	8,2		
12	sample 9	9,3		
13	sample 10	8,4		
14	mean	8,4		
15	SD	0,35		
16	CV%	4,18		
17	single value <> 20% mean?	0		
18	mean within reference range?	yes		
19	CV% < 5%?	yes		



Cell	Function
A14	=AVERAGE(B4:B13)
A15	=STDEV(B4:B13)
A16	=B15*100/B14
A17	=COUNTIFS(B4:B13,"<"&(B14-(B14*0.2)))+COUNTIFS(B4:B13,">"&(B14+(B14*0.2)))
A18	=IF(ISNUMBER(B4)=FALSE,"",IF(B14>\$D\$2,"no",IF(B14<\$C\$2,"no","yes")))
A19	=IF(ISNUMBER(B4)=FALSE,"",IF(B16<=5,"yes","no"))



Lab Manager (signature)

Neclin Seul

7. Closure

Study data has determined that the system described in this document meets all criteria outlined in this Performance Qualification protocol. All exceptional conditions if any have been addressed. The system is ready for specific usage.

The analyzer passed the performance quality check. The analyzer didn't pass the performance quality check (see additional notes).						
	System	☐ HumaStar 100 ☐ HumaStar 200 ☐ HumaStar 300 SR ☐ HumaStar 600	Serial Number: 21191146004 SW Version: 0.44.2.15 Setting-Database Version: 1.36			
	Date 30-NOV-2019	Service engineer / Application Specialist (printed name) MUBASHIR WALI	Service engineer / Application Specialist (signature)			

8. Additional notes

Lab Manager (printed name)

NEELIMA SACHAN

Date

30-NOV-2019



HumaStar 100 HumaStar 200 HumaStar 300SR Installation quality check

Revision list

Revision	Date	Description	Editor
1	2016/02/26	First revision	Mathias Kamprath
2	2018/06/20	Review and extension to HumaStar 300SR	Mathias Kamprath
3	2019/01/28	Repetition of all calibration steps added	Mathias Kamprath
4	2019/02/22	Serial number field added	Mathias Kamprath

Lab Name Narayan Pathology And Biopsy Centre Add- 117/22 Sarvodaya Nagar Kanpur

Special tools

Volt meter or multi meter (V and mV). E. g. Human catalog number 60200224

Accompanying documents

- A) HSB Power Surge Protector & online UPS incl. ground check.pdf
- B) HumaStar 100/200 Service Manual, revision 04/2015/09
- C) HumaStar 300SR Service Manual, revision 01/2018-FEB-09
- D) Touch screen monitor documentation (optional)
- E) Printer documentation (optional)

Installation quality check

Step	Check	Expected result	Result	Final remark
		Main power supply		
1	Measure the grounding voltage between neutral and ground of the main power line. See document A).	Less than 2V.	1.3v	OKAY



Step	Check	Expected result	Result	Final remark
2	Connect the power surge protector socket to the main power. If the EU plug doesn't fit use either the UK or the US adapter. See document A).	Green and red LEDs are on.	SUPPLY OKAY	DONE
3	Connect the on-line UPS to one of the power protection sockets and switch on the online UPS. See document A).	The on-line UPS starts charging the battery. The wrong wiring alarm is off. Wait for 100% charge of the battery before switching on the analyzer.	CONNECTED	OKAY

Installation of the analyzer,
PC (incl. mouse and keyboard),
external barcode scanner (HumaStar 300SR)
monitor (touch screen optional),
printer (optional)

and bottles for system solution (blue), special wash solution (green), normal waste (red) and special waste (yellow, HumaStar 300SR)

4	Place the analyzer on a work bench. Remove all transportation protection for the: • top cover, • sampling arm(s), • internal barcode reader cover (HumaStar 100/200), • wash station top cover (HumaStar 200).	Enough space (150 mm recommended) on the left, rear and right side and approx. 55-60 mm underneath. The analyzer is horizontally aligned.	ALL DONE	OKAY
5	Place the other electronic components on the right side of the analyzer. (recommended)		PLACED	DONE
6	Place the system solution, special wash solution, normal waste and special waste (HumaStar 300SR) bottles on the left side of the analyzer. (recommended)		PLACED AT BOTTOM	DONE



Step	Check	Expected result	Result	Final remark
7	Establish all connections.	As described in document B) "2.3.5 Installation" (HumaStar 100/200) or document C) "3.3.5 Installation" (HumaStar 300SR).	ESTABLISHED	DONE
8	Switch on the analyzer.	The inner plate shakes three times, the peristaltic pump 7 (and 9, HumaStar 300SR) turn for a second and the pinch valve(s) switch on and off.	SWITCHED ON	DONE
9	Connect the external barcode scanner (HumaStar 300SR) to the PC.		N/A	N/A
10	Switch on the monitor and the PC.	Log on as "Support" user. If not pre-installed, install the HI software as described in document B) "18 HI Software installation/update" (HumaStar 100/200) or document C) "8 HI Software installation" (HumaStar 300SR).	SWITCHED ON INSTALLED HI	DONE
11	Touch screen monitor and printer only.	If not pre-installed, install the driver(s) as described in the accompanying documentation D) and E).	N/A	N/A
12	Start the HI program as "Installer".	Analyzer connects to the HI software.	STARTED	DONE
13	Go to the Terminal program and repeat all calibration steps. HS100/200: 21 steps HS300SR: 39 steps	Every calibration step has to be finished successfully.	SUCCESFULLY DONE	DONE



Revision 4

Closure

Serial number of the analyzer: 2 1 1 9 1 1 4 6 0 0 4 The analyzer passed the installation quality check. The analyzer didn't pass the installation quality check. Note the next steps to get the analyzer in condition to pass the installation quality check. Date Service engineer (printed name) Service engineer (signature) fleval. 30-NOV-2019 MUBASHIR WALI

1. Additional notes



HumaStar 100 HumaStar 200 HumaStar 300SR Operation quality check

Revision list

Revision	Date	Description	Editor
1	2016/02/26	First revision	Mathias Kamprath
2	2016/03/02	SD formula and EXCEL example changed	Mathias Kamprath
3	2018/06/20	Review and extension to HumaStar 300SR	Mathias Kamprath
4	2019/02/22	Serial number field added	Mathias Kamprath

Lab Name Narayan Pathology And Biopsy Centre Add- 117/22 Sarvodaya Nagar Kanpur

Special materials

- Wash additive (18971)
- Special wash solution (18974)
- 0.9% NaCl solution
- Serodos control (13951)
- HumaTrol P control (13512)
- AutoCal multi-calibrator (13160)
- Glucose liquicolor reagent
- · Calcium liquicolor reagent

Accompanying documents

- A) HumaStar 100/200 User Manual, revision 02/2013-03
- B) HumaStar 100/200 Service Manual, revision 04/2015/09
- C) HumaStar 300SR User Manual, revision 02/2017-11
- D) HumaStar 300SR Service Manual, revision 01/2018-FEB-09



Operation quality check

Step	Check	Expected result	Result	Final remark
1	Prepare the system solution, the special wash solution and the dilution bottles.	PREPARED	OKAY	DONE
2	Switch on the analyzer and run the start-up procedure.	No error messages. All cuvettes shown in green in HI > Maintenance > reaction cuvettes (HumaStar 100/200) or HI > Maintenance > Special > Reaction cuvettes (HumaStar 300SR].	NO MESSAGE ALL GREEN	DONE
3	Prepare the AutoCal multi- calibrator and the two controls Serodos and HumaTrol.	Place a cup of AutoCal, Serodos and HumaTrol on the sample tray.	PREPARED & PLACE	DONE
4	Prepare the Glucose and/or GOT and/or Calcium reagent(s). GLU & GOT	Place the reagent bottle(s) on the reagent tray and run the level check. All volumes have to be recognized.	PLACED & CHECKED THE LEVEL	DONE
5	Use Serodos as sample material.	Place a cup of "sample" material on the sample tray. When all tests are to be performed, better place two cups on the sample tray.	PLACED 2 CUPS	DONE
6	Generate a work list.	Per reagent the "sample" material has to be tested 10 times.	PLACED THE SAMPLE	DONE
7	Run the work list.		RUN	DONE



Step	Check	Expected result	Result	Final remark
8	Evaluate the results as following: $mean = \sum_{i=1}^{10} sample i$ $SD = \sqrt{\frac{\sum_{i=1}^{10} (sample \ i - mean)^2}{9}}$ $CV\% = \frac{SD*100}{mean}$ Easy to calculate in an EXCEL sheet using the appropriate formulas. See also 6. Example for calculations in EXCEL.	The mean of all ten "sample" results has to be in the reference range of the Serodos control. The CV% has to be less than 5%. Only one "sample" result may deviate more than +/- 20% from the mean. The mean and the SD of the remaining nine results have to be recalculated.	GLU CV= 2.5% SGOT CV= 1.8%	OKAY



Closure

Serial number of the analyzer: 2 1 1 9 1 1 4 6 0 0 4 The analyzer passed the operation quality check. The analyzer didn't pass the operation quality check. Note the next steps to get the analyzer in condition to pass the operation quality check. Service engineer (signature) Date Service engineer (printed name) 30-NOV-2019 MUBASHIR WALI

Additional notes



Example for calculations in EXCEL

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A19	=IF(ISNUMBER(B4)=FALSE,"",IF(B16<=5,"yes","no"))





Training Certificate

This is to certify that

Ms Smriti Gupta Has been trained on

Humastar 200

Model of Humastar 200 Biochemistry Analyzer The training was conducted by Product Experts

Narayan Pathology & Biopsy Centre

117/22, Sarvodya Nagar Opp J.L RohtagiEye Hospital Near Baba Bhoothnath Ashram Kanpur-208005

Dated: 16-12-2019

Star Human SciencesPvt. Ltd. New Delhi, INDIA -110 005

Training Certificate

This is to certify that

Mr Ranjeet Kumar Has been trained on

Humastar 200

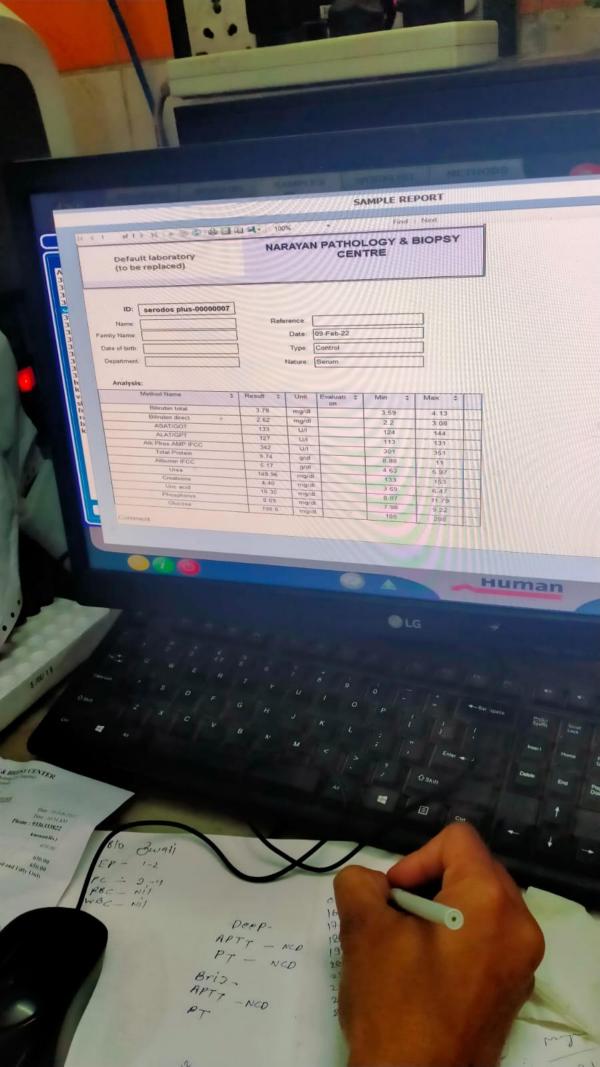
Model of Humastar 200 Biochemistry Analyzer The training was conducted by Product Experts

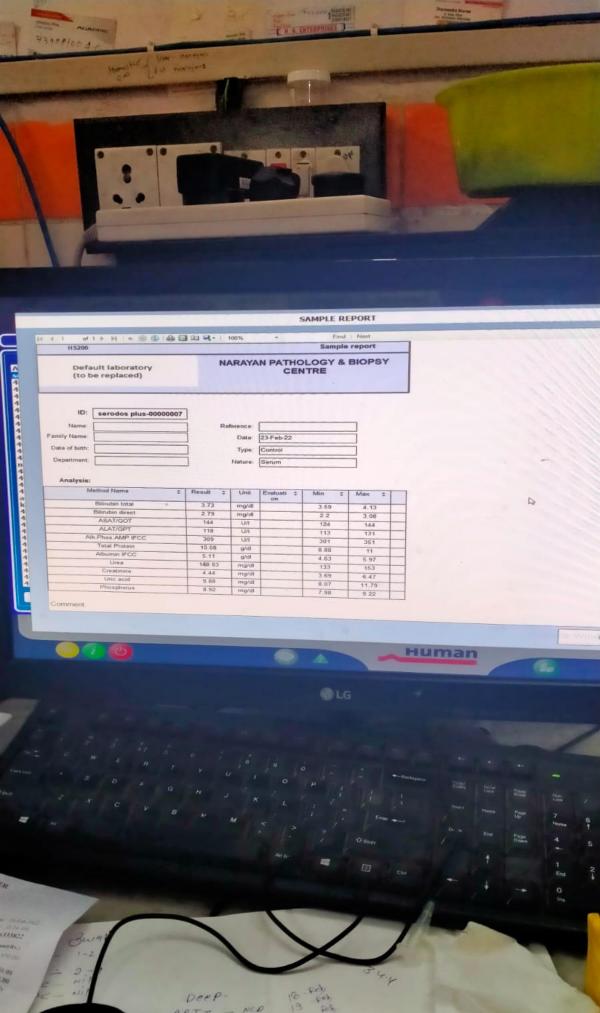
Narayan Pathology & Biopsy Centre

117/22, Sarvodya Nagar Opp J.L RohtagiEye Hospital Near Baba Bhoothnath Ashram Kanpur-208005

Dated: 16-12-2019

Star Human SciencesPvt. Ltd. New Delhi, INDIA -110 005

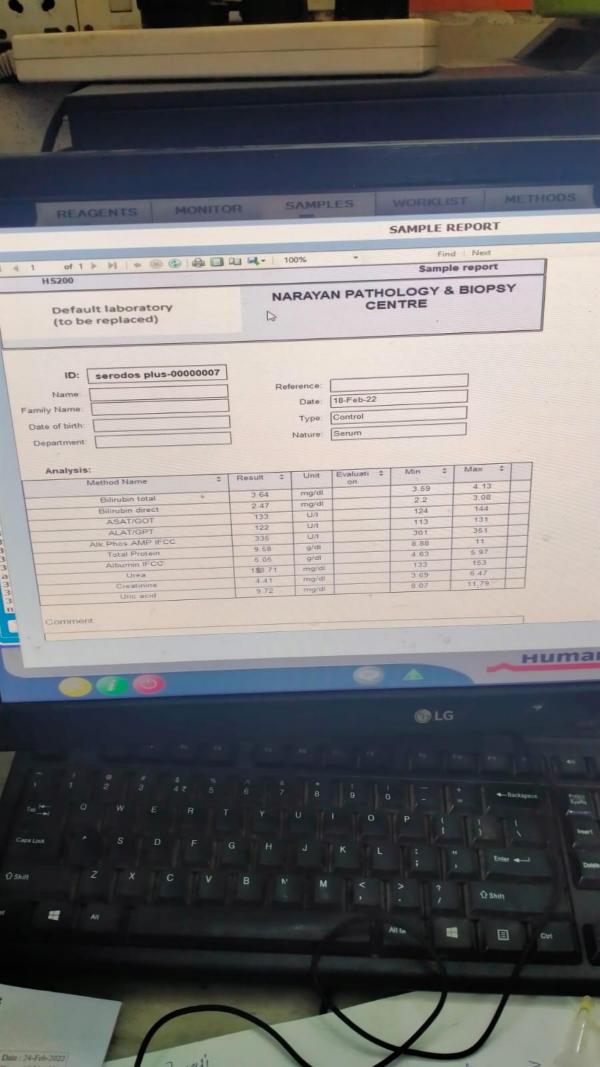


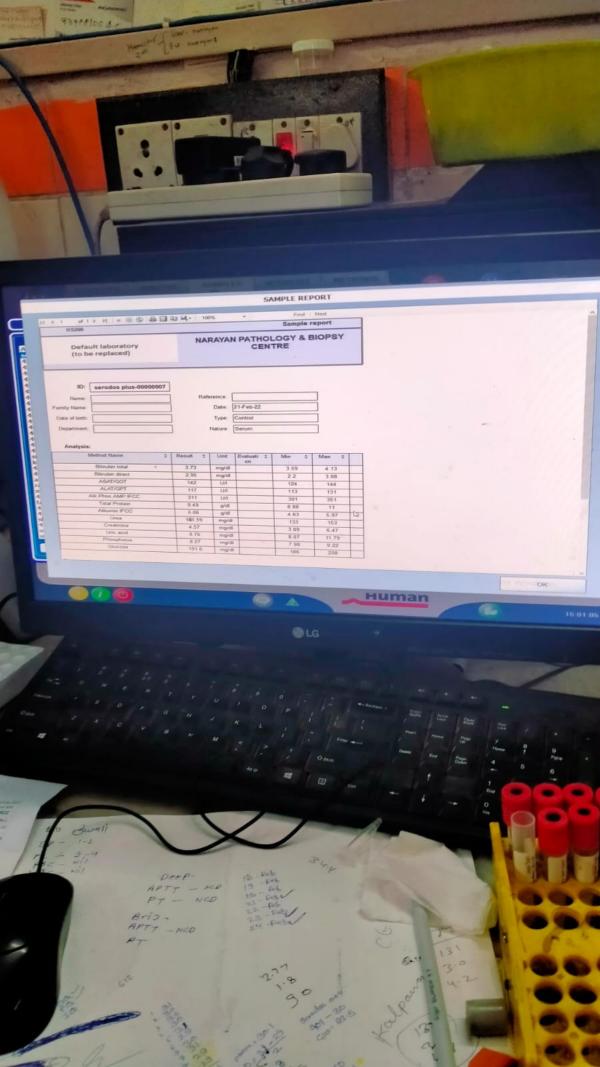


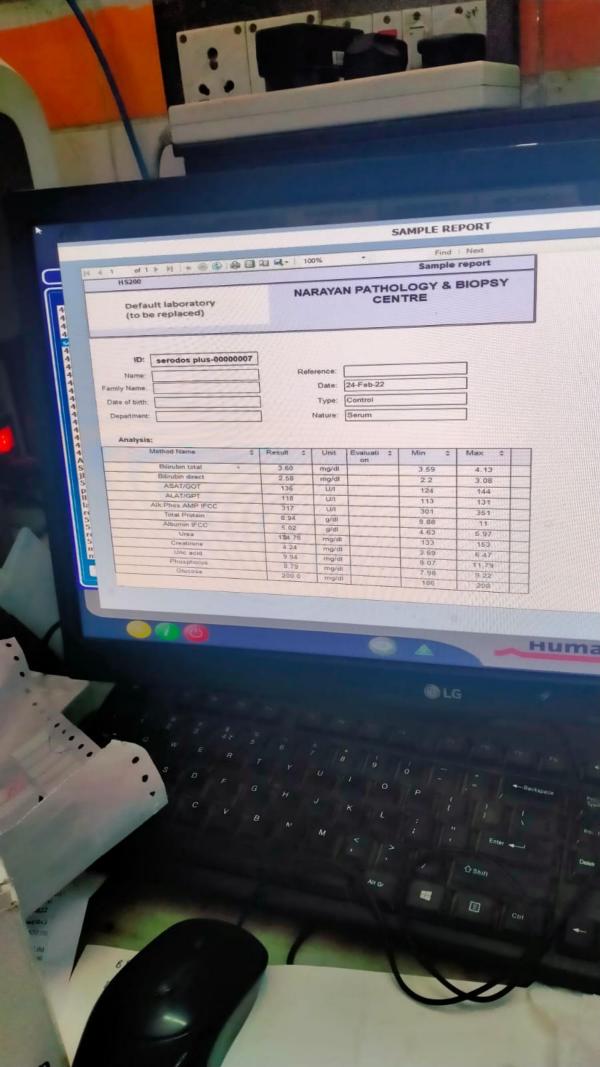
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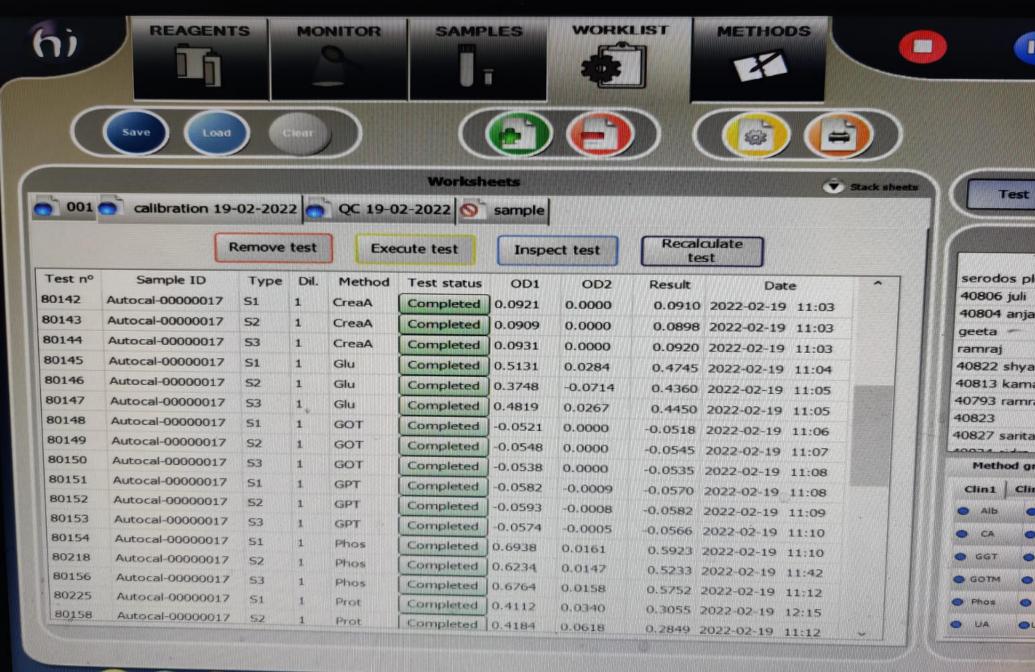
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Test

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		Remove			oute test	Inspec	t test	Recalc			
Test no	Sample ID	Туре	Dil.	Method	Test status	OD1	OD2 0.0340	Result 0.3055	Date 2022-02-19		•
80225	Autocal-00000017	51	1	Prot	Completed	0.4112	0.0618	0.2849	2022-02-19	11:12	
80158	Autocal-00000017	S2	1	Prot	Completed	0.4252	0.0644	0.2891	2022-02-19	11:13	
30159	Autocal-00000017	53	1	Prot	Completed	0.5815	0.0040	0.5099	2022-02-19	11:14	
80160	Autocal-00000017	S1	1	Trig	Completed	0.5805	0.0032	0.5097	2022-02-19	11:14	
80161	Autocal-00000017	52	1	Trig	Completed	0.5655	0.0049	0.4930	2022-02-19	11:15	
80162	Autocal-00000017	53	1,	Trig	Completed	0.2185	0.0343	0.1630	2022-02-19	11:15	
80163	Autocal-00000017	51	1	UA	Completed	0.2082	0.0247	0.1623	2022-02-19	11:15	
80164	Autocal-00000017		1	UA	Completed	0.2131	0.0262	0.1657	2022-02-19	11:16	
80165	Autocal-00000017		1	UA	Completed	4	0.0000	-0.0981	2022-02-19	11:16	
80166	Autocal-0000001		1	UreaUV	Completed	-0.0974	0.0000	-0.0922	2022-02-19	11:16	
80167	Autocal-0000001		1	UreaUV	Completed	-0.1120	0.0000	-0.1068	2022-02-19	11:59	
80223	Autocal-0000001	7 53 U	1	Alb	Completed	0.9083	0.0973	2.77	2022-02-19		(p)
80195	geeta	- 10	1	Glu	Completed	-	0.0601		2022-02-19		4
80196	geeta	-\u0	1	Prot	Completed	0.2624	0.0519		2022-02-19		
80197	-	- N	1	Glu	Completed	0.3903	0.0582		2022-02-19		
80199	}	N	1	Prot	Completed	0.1565	0.0541	0.95	2022-02-19	11:45	~













