



भारत सरकार/Government of India
स्वास्थ्य और परिवार कल्याण मंत्रालय/ Ministry of Health and Family Welfare
प्रधानमंत्री स्वास्थ्य सुरक्षा योजना/PMSSY
अखिल भारतीय आयुर्विज्ञान संस्थान/All India Institute of Medical Sciences
मंगलगिरि, आंध्र प्रदेश/Mangalagiri, Andhra Pradesh

www.aiimsmangalagiri.edu.in

Ref: AIIMSM-ADMN/PROC(CPPP)/45/2025-Procurement AIIMS MG

Date: 13-11-2025

Call for Objection

Subject: Inviting comments/objection, if any before declaring proprietary article for procurement of “**Large throughput Dry Chemistry Fully Automated integrated system (Chemistry & immunoassays) lab on Reagent Rental Basis for a period of 05 years**” for the Department of Biochemistry AIIMS Mangalagiri.

Biochemistry Department, AIIMS Mangalagiri has to procure “**Large throughput Dry Chemistry Fully Automated integrated system (Chemistry & immunoassays) lab on Reagent Rental Basis for a period of 05 years**” through Proprietary Article basis.

The proposal has been submitted by M/s Ortho Clinical Diagnostics India Pvt. Ltd., having its registered office at 403, Leela Business Park, Andheri Kurla Road, Andheri East, Mumbai – 400059, India, which is the exclusive marketer in India for Ortho Clinical Diagnostics, Inc., USA, the legal manufacturer of clinical diagnostic equipment namely VITROS 4600 Chemistry System, VITROS 350 Chemistry System, and VITROS 5600 / VITROS XT 7600 Integrated Systems. The product is proprietary to Ortho Clinical Diagnostics, Inc., USA, and the Proprietary Article Certificate has been attached and uploaded on the Institute website.

The above documents are being uploaded for open information to submit objections, comments if any from any manufacturer/supplier before declaring proprietary article of the said equipment/items to be procured, within 10 days (i.e. 23-11-2025) from the date of issuance/uploading of the notification.

The objection should be raised in the technical compliance sheet as enclosed in Annexure -I, if any Firm claiming suitability of their product with respect to specification mentioned.

The comments should be sent to the office of Procurement Cell, Room no: 2151, Logistic block at AIIMS Mangalagiri in a sealed envelope with above reference on or before 23-11-2025 up to 05:00 PM from the date of uploading on institutional website, failing which it will be presumed that any other manufacture/vendor is having no comment to offer and case will be decided on merits.

-Sd-

AAO (Procurement)
AIIMS Mangalagiri

P-3 FORM
(To be attached with P-2 form for Proprietary items)
AIIMS Mangalagiri

PROPRIETARY ARTICLE CERTIFICATE

It is certified that the Article/Equipment Reagents & Consumables for Technology: Micro slide (DRY CHEMISTRY SYSTEM) for routine chemistry and micro tip technology for immunoassay required in the P-2 form should be purchased from M/s Ortho Clinical Diagnostics India Pvt. Ltd having its Registered office at 403, Leela Business Park, Andheri Kurla Road, Andheri East, Mumbai -400059, India. To the best of my knowledge, they are the sole agents/distributors of the sole manufacturers M/s Ortho Clinical Diagnostics, Inc., USA. No other make/brand will be suitable for our purpose for the following reasons:-

- a. Analyzer-specific compatibility – The reagents, calibrators, and consumables are specifically validated and programmed for the Integrated dry chemistry based clinical chemistry analyser and immunoassay system vitros 5600/7200. Using non-genuine reagents may cause errors, compromise quality of results, or be incompatible with the system software and onboard applications.
- b. Assured quality and regulatory compliance – Only Ortho Clinical Diagnostics –supplied reagents are supported with proper certificates of analysis, traceability to international standards, and regulatory approvals (CE-IVD/FDA). This ensures accuracy, reproducibility, and compliance with NABL/ISO guidelines in clinical laboratory practice.
- c. Warranty, service, and instrument performance – Use of third-party reagents can void the manufacturer's warranty, affect calibration protocols, and interfere with preventive maintenance. Proprietary reagents guarantee instrument uptime, service support, and adherence to manufacturer-recommended performance specifications.

These features are important for reliable and reproducible patient results and to the best of knowledge are not available in any other product.

Signature of Indenter
with date and Stamp

Montosh Chakraborty
12.11.25

DR. MONTOSH CHAKRABORTY, MD
Additional Professor, Biochemistry
AIIMS, Mangalagiri

Recommendation by HoD: *Recommended & forwarded*

Signature of Head of Department /Section

Desai
Prof. Dr. DESAI VIDYA SRIPAD, MD
HOD, DEPARTMENT OF BIOCHEMISTRY
AIIMS, MANGALAGIRI

N.B.: The indenter before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature manufactured under patent laws.

Technical Specifications for Large throughput Dry Chemistry Fully Automated integrated system (Chemistry & immunoassays) on Reagent Rental Basis

Technical Specifications:

1. Analytical system should be Fully automated, closed, discrete, multi-channel, random-access, integrated (clinical chemistry and Immunoassay) System with a throughput more than 800 tests per hour for biochemistry & Minimum 185 tests per hour for immunoassay with a capability to be connected to total lab automation system. Minimum 2 high end integrated systems should be available at any point of time.

2. **Technology: Micro slide (DRY CHEMISTRY SYSTEM) for routine chemistry and micro tip technology for immunoassay**

3. The complete system should be the latest on the production line, certified by ISO, UL, USFDA and European CE with 4 digit notified body number. Suo moto upgradation of any new technology must be undertaken by the supplier free of cost. No refurbished equipment will be accepted.

4. Analytical principles should include Colorimetry (Endpoint, rate, fixed point), Potentiometry (Direct ISEs), Immuno-rate, Turbidimetric & Enhanced Chemiluminescence for immuno-assay.

5. Test menu should include all the routinely done clinical biochemistry parameters including general chemistry, Diabetes, profile for Anemia, renal, liver panel tests, Lipids, calcium, electrolytes (Na, K, Cl, lithium), enzymes as ALT, AST, ALP, amylase, Lipase, CK-Nac, CK-MB, Autoimmune, Cardiac, Drugs of Abuse, Inflammatory, Toxicology, HbA1c, Therapeutic Drug Monitoring, Specialty parameters, hormones, vitamins, tumour markers, immunoglobulins and urinary and other body fluid parameters which can be modified.

6. Onboard Test Capacity: Should have minimum of 145 reagent positions, Minimum 100 for Chemistry & 30 for Immuno-assays.

7. The instrument should have facility for variable incubation for different parameters as per test protocol.

8. Should have facility to replenish reagents and consumables without interrupting system operation.

9. It should use disposable tips for sample aspiration & dispensing to eliminate carryover & cross contamination for both chemistry and Immunoassay.

10. Electrolyte (Na, K, Cl) should be based on Direct ISE method and should not use fixed electrode for measurement.

P. Sripad
Th. M. S. S. S.
G. S. S. S.
Dr. M A BARI SIDDQUI, MD, DNB
Associate Professor, Biochemistry
AIIMS, Mangalagiri

Montosh Chakraborty
Dr. MONTOSH CHAKRABORTY, MD
Additional Professor, Biochemistry
AIIMS, Mangalagiri

Prof. Dr. DESAI VIDYA SRIPAD, MD
HOD, DEPARTMENT OF BIOCHEMISTRY
AIIMS, MANGALAGIRI

11. Should have provision for STAT sample analysis.
12. Should be compatible for Serum, plasma, urine, whole blood, and other body fluids sample such as Pleural, peritoneal fluid, CSF, and synovial fluid.
13. Should be able to use sample volume of 2 - 30 μ L
14. Sample probe should have liquid level sensor, sample clot detection and crash prevention and washing facility.
15. Should have an automated sample quality analysis system for sample viscosity, Lipemia, hemolysis, icterus indices and clot and bubbles for both chemistry and Immunoassay without affecting the throughput of system.
16. Sample Capacity: 80 samples in Universal Sample Tray and should be able to use multiple tubes of different sizes.
17. Sample Trays must accommodate 5mL, 7mL, 10mL primary and secondary collection tubes, 1.5mL micro-collection containers in micro-sample cups and 0.5mL and 2.0mL cups.
18. Reagents: Microslides for chemistry and No mixing or reconstitution should be required for immunoassay reagent packs, should have onboard stability of minimum 50 days, and should have facility to replenish reagents without interruption.
19. Should have the inbuilt refrigeration system with controlled temperature (2°C to 8°C) and humidity for reagent storage to maintain the stability of reagents on board.
20. Should have an inbuilt bar code reading facility for both samples and reagents.
21. The system must have the facility for real time reagent tracking and management with data regarding reagent lot number, expiry date, number of tests utilized (utilized for calibration, QC, patient results, repeat tests) and available.
22. The system must facilitate inventory management by providing average consumption of reagents in a specific time duration.
23. Should have facility for positive sample identification, real time test requisition downloading from host.
24. Clinical chemistry assays should be stable up to lot change with random-access calibration, Bar-coded calibrators Clinical Chemistry assays and should have minimum 22 days Calibration stability for all immune-assay parameters.
25. Certificate of Traceability for calibrators, traceable to national/international reference Standards to be submitted by the vendor.
26. Should have in-built facility for Quality control data analysis such as Westgard rules, Twin Plot and Levey Jennings graphs, auto QC, cooled QC positions and Six sigma.

P. Sripad
T. H. Manohar
G. Srinivasan
Dr. S. S.

Dr. M A BARI SIDDIQUI, MD, DNB
Associate Professor, Biochemistry
AIIMS, Mangalagiri

Montosh Chakraborty
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AIIMS, Mangalagiri

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AIIMS, MANGALAGIRI

27. The system should have a facility for automated pre and post auto dilution of samples with ratio of 3 to 100 times.

28. Should have facility for automatic Rerun, Repeat and reflex testing.

29. System Startup: 24-hour ready mode, No manual primes, purges, washes or tubing maintenance.

30. Should have facility for Uni- and bi-directional LIS interfacing And HMIS interfacing. Autovalidation software and middle ware will be provided at no extra cost to the institute

31. Requisite number of compatible 27" all in one computers (5) with latest processor and motherboard, colored touch monitor, 1 TB hard drive, CD/DVD drive, 16 GB SSD memory, Windows XP*/, compatible OS with existing HIMS and LIS with Heavy duty laser printer(3) should be provided.

32. The system should have process monitoring software to monitor every step during the process and give report for every test performed. Should have facility for complete backup of the database for calibration, control and patient sample results. At least 5,000 patient results storage. There should be provision to upgrade the number or quantity and quality of analysers to maintain the turn around time depending on the workload at no extra cost to the institute.

33. Operating temperature: 15°-30°C / 59°-86°F & Electrical requirement 220-240 V AC - 50 Hz.

34. Suitable UPS with backup minimum for 1 hour should be provided.

35. Should have no or minimum requirement of water.

36. Should provide a PM kit and necessary accessories along with equipment.

37. Should provide reagents, calibrators, third party controls and consumables required for initial installation and validation of all the parameters.

38. The calibrators, consumables (disposable tips, cuvettes), electrodes, and any accessories required by the analyzer should be provided free of cost during the entire tenure of contract. The storage including -20 degrees Celsius deep refrigerators should be provided to accommodate the dry chemistry reagents and consumables accordingly at no extra cost

39. All Chemistry Reagents should be US FDA approved.

40. Should be compatible for transport of specimens from conveyor belt, into and from the system at a later stage.

41. Operator manual, instructions for use and on CD to be provided.

P. Sriprad
T. S. Mandal
Gangaraju
om
Dr. M A BARI SIDDIQUI, MD, DNB
Associate Professor, Biochemistry
AIIMS, Mangalagiri

Montosh Chakraborty
Dr. MONTOSH CHAKRABORTY, MD
Additional Professor, Biochemistry
AIIMS, Mangalagiri

pele
Prof. Dr. DESAI VIDYA SRIPAD, MD
MOD, DEPARTMENT OF BIOCHEMISTRY
AIIMS, MANGALAGIRI

42. Should provide Air conditioner – 02 No. or more for the maintenance of ambient temperature and humidity required for maintenance of equipment and reagents stability and look after the maintenance during the contract tenure.

43. Should provide Certificate of instrument manufacture date and place of manufacturing facility.

44. Maintenance: Complete periodic maintenance and replacement of spares of analyzer system, and supporting equipment (computer, AC, Water purifier, UPS, peripherals, centrifuges as required depending on workload, refrigerators for the storage of reagents etc.) at no extra cost. All consumables and spares such as ISE electrodes, tubings, cuvettes, lamp, filters etc. which needs to be replaced as a part of periodic maintenance of the supplied equipment including UPS and water purification system must be supplied by the bidder at no extra cost.

45. The company shall upkeep the equipment for 365 days a year. The company shall maintain the instrument with absolute zero downtime so that the entire workload should be completed with the same throughput.

46. If the situation warrants / delay in availability of equipment due to delay in service or maintenance, a back-up of another analyzer which can work with the same reagents should be provided by the vendor under the same terms & conditions and maintaining the same turn around time

47. Where the institution purchases reagents more than Indian Rupees two crores in a year, company agrees to place and install total laboratory automation system (including but not limited to sample conveyor tracks, decapper, sealers, etc) at no additional cost to institution.

48. Technical Support will be provided on site for 6 months from the date of installation to ensure proper training and handholding of laboratory technologist /operator for smooth function of the analyzer. A Biomedical engineer will be present permanently in station to attend trouble shooting with relation to track system and overall analytical system from the company's end at no extra cost to the institute. Provision should be made to have breakdown time of not more than 3 hours.

49. Analyzer can be taken back if the institute is dissatisfied about the performance of the analyzer and service of the company or not use it in regular basis within 30 days' notice period after mutual discussion with the competent authority of the institution.

50. The vendor should provide all the facilities / accessories / software for integration into LIS, HMIS as and when it materializes at AIIMS Mangalagiri.

51. The prices of the reagents will be quoted in the annexure and will be kept constant for the next 5 years

52. The installation should be available in other Institutes of National Importance

P. Sripriya
T. H. Manjula
G. Anurag
Dr. M A BARI
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Associate Professor, Biochemistry
AIIMS, Mangalagiri

Montosh Chakraborty
Dr. MONTOSH CHAKRABORTY, MD
Additional Professor, Biochemistry
AIIMS, Mangalagiri

Dr. Desai
Dr. DESAI VIDYA SRIPAD, MD
HOD, DEPARTMENT OF BIOCHEMISTRY
AIIMS, MANGALAGIRI

Date: 10 July 2023

Proprietary Certificate

To Whom So Ever It May Concern,

Ortho Clinical Diagnostics, Inc., USA is a legal manufacturer of clinical diagnostics equipment VITROS 4600 Chemistry system, VITROS 350 Chemistry system, VITROS 5600 Integrated System/ VITROS XT 7600 Integrated System & is proprietary product of Ortho-Clinical Diagnostics, Inc., USA and is exclusively marketed in India by Ortho Clinical Diagnostics India Pvt. Ltd., having its Registered office at 403, Leela Business Park, Andheri Kurla Road, Andheri East, Mumbai -400059, India.

Below products are proprietary product of Ortho Clinical Diagnostics with manufacturer Ortho Clinical Diagnostics, UK or Ortho Clinical Diagnostics, USA and can only be used on VITROS 4600 Chemistry system, VITROS 350 Chemistry system, VITROS 5600 Integrated System/ VITROS XT 7600 Integrated System & no other products can be used on these instrument systems.

Sr. No.	Product Code	Product Description	Pack Size
1	1037274	VITROS Chemistry Products ACET Slides	90 Tests
2	1988211	VITROS Chemistry Products ALB Slides	90 Tests
3	8196057	VITROS Chemistry Products ALB Slides	250 Tests
4	8046872	VITROS Chemistry Products ALC Slides	90 Tests
5	1053180	VITROS Chemistry Products ALKP Slides	300 Tests
6	1655281	VITROS Chemistry Products ALT Slides	250 Tests
7	1721869	VITROS Chemistry Products AMON Slides	300 Tests
8	1726926	VITROS Chemistry Products AMON Slides	90 Tests
9	1202670	VITROS Chemistry Products AMYL Slides	300 Tests
10	8112724	VITROS Chemistry Products AMYL Slides	90 Tests
11	8433815	VITROS Chemistry Products AST Slides	300 Tests
12	1612365	VITROS Chemistry Products BuBc Slides	90 Tests
13	8383051	VITROS Chemistry Products BuBc Slides	300 Tests
14	8102204	VITROS Chemistry Products BUN/UREA Slides	300 Tests
15	1450261	VITROS Chemistry Products Ca Slides	300 Tests
16	1914605	VITROS Chemistry Products CHE Slides	300 Tests
17	8004707	VITROS Chemistry Products CHE Slides	90 Tests
18	1669829	VITROS Chemistry Products CHOL Slides	300 Tests
19	8478034	VITROS Chemistry Products CK Slides	90 Tests
20	8479396	VITROS Chemistry Products CK Slides	300 Tests
21	8058232	VITROS Chemistry Products CKMB Slides	300 Tests
22	8001133	VITROS Chemistry Products CKMB Slides	90 Tests

Sr. No.	Product Code	Product Description	Pack Size
23	8445207	VITROS Chemistry Products Cl- Slides	250 Tests
24	8892382	VITROS Chemistry Products CRBM Slides	90 Tests
25	6802584	VITROS Chemistry Products CREA Slides	300 Tests
26	8097990	VITROS Chemistry Products CRP Slides	90 Tests
27	1926740	VITROS Chemistry Products CRP Slides	250 Tests
28	8343386	VITROS Chemistry Products DGXN (Digoxin) Slides	90 Tests
29	6801895	VITROS Chemistry Products dHDL Slides	300 Tests
30	6802469	VITROS Chemistry Products dHDL Slides	90 Tests
31	8262396	VITROS Chemistry Products ECO2 Slides	300 Tests
32	1924547	VITROS Chemistry Products Fe Slides	90 Tests
33	1515808	VITROS Chemistry Products Fe Slides	300 Tests
34	8257289	VITROS Chemistry Products GGT Slides	250 Tests
35	8157596	VITROS Chemistry Products K+ Slides	250 Tests
36	8150112	VITROS Chemistry Products LAC Slides	90 Tests
37	8433880	VITROS Chemistry Products LAC Slides	300 Tests
38	8384489	VITROS Chemistry Products LDH Slides	250 Tests
39	8318925	VITROS Chemistry Products Li Slides	300 Tests
40	1632660	VITROS Chemistry Products Li Slides	90 Tests
41	1668409	VITROS Chemistry Products LIPA Slides	300 Tests
42	8297749	VITROS Chemistry Products LIPA Slides	90 Tests
43	8255093	VITROS Chemistry Products Mg Slides	300 Tests
44	1921204	VITROS Chemistry Products Mg Slides	90 Tests
45	8379034	VITROS Chemistry Products Na+ Slides	250 Tests
46	1513209	VITROS Chemistry Products PHOS Slides	300 Tests
47	8298671	VITROS Chemistry Products PHYT Slides	90 Tests
48	8208431	VITROS Chemistry Products PROT Slides	90 Tests
49	1314343	VITROS Chemistry Products SALI Slides	90 Tests
50	8159931	VITROS Chemistry Products TBIL Slides	300 Tests
51	1307164	VITROS Chemistry Products THEO Slides	90 Tests
52	8301764	VITROS Chemistry Products THEO Slides	300 Tests
53	8392292	VITROS Chemistry Products TP Slides	250 Tests
54	1336544	VITROS Chemistry Products TRIG Slides	300 Tests

Sr. No.	Product Code	Product Description	Pack Size
55	8329930	VITROS Chemistry Products TRIG Slides	90 Tests
56	6800120	VITROS Chemistry Products UPRO Slides	90 Tests
57	1943927	VITROS Chemistry Products URIC Slides	300 Tests
58	1707801	VITROS Chemistry Products GLU Slides	300 Tests
59	6844430	VITROS Chemistry Products LDHI Slides	250 Tests
60	6844471	VITROS Chemistry Products Cl- Slides	250 Tests
61	6844288	VITROS Chemistry Products ALTV Slides	300 Tests
62	6844294	VITROS XT Chemistry Products UREA-CREA Slides	300 Tests
63	6844292	VITROS XT Chemistry Products TRIG-CHOL Slides	300 Tests
64	6844295	VITROS XT Chemistry Products GLU-Ca Slides	300 Tests
65	6844296	VITROS XT Chemistry Products TBIL-ALKP Slides	300 Tests
66	6844291	VITROS XT Chemistry Products ALTV-AST Slides	300 Tests
67	6844293	VITROS XT Chemistry Products ALB-TP Slides	250 Tests
68	1882208	VITROS Chemistry Products Calibrator Kit 1	4sets/ Box
69	1662659	VITROS Chemistry Products Calibrator Kit 2	4sets/ Box
70	1290709	VITROS Chemistry Products Calibrator Kit 3	4sets/ Box
71	1204668	VITROS Chemistry Products Calibrator Kit 4	4sets/ Box
72	1149764	VITROS Chemistry Products Calibrator Kit 5	4sets/ Box
73	1204247	VITROS Chemistry Products Calibrator Kit 6	4sets/ Box
74	1320498	VITROS Chemistry Products Calibrator Kit 7	4sets/ Box
75	8578163	VITROS Chemistry Products Calibrator Kit 8	4sets/ Box
76	8568040	VITROS Chemistry Products Calibrator Kit 9	4sets/ Box
77	6800189	VITROS Chemistry Products Calibrator Kit 10	2sets/ Box
78	6801896	VITROS Chemistry Products Calibrator Kit 25	2sets/ Box
79	8466492	VITROS Chemistry Products Liquid Performance Verifier I	6 Bottles/ Box
80	1384007	VITROS Chemistry Products Liquid Performance Verifier II	6 Bottles/ Box
81	8067324	VITROS Chemistry Products Performance Verifier I	12 Sets/ Box
82	8231474	VITROS Chemistry Products Performance Verifier II	12 Sets/ Box
83	8721508	VITROS Chemistry Products Isoenzyme Performance Verifier I	6 Sets/ Box
84	8748220	VITROS Chemistry Products Isoenzyme Performance Verifier II	6 Sets/ Box
85	8936049	VITROS Chemistry Products CRP Performance Verifier I	6 Sets/ Box
86	8597452	VITROS Chemistry Products CRP Performance Verifier II	6 Sets/ Box

Sr. No.	Product Code	Product Description	Pack Size
87	6800190	VITROS Chemistry Products UPRO Performance Verifier I	6 Bottles/ Box
88	6800191	VITROS Chemistry Products UPRO Performance Verifier II	6 Bottles/ Box
89	8962540	VITROS Chemistry Products TDM Performance Verifier I	6 Bottles/ Box
90	1792357	VITROS Chemistry Products TDM Performance Verifier II	6 Bottles/ Box
91	8182172	VITROS Chemistry Products TDM Performance Verifier III	6 Bottles/ Box
92	8867541	VITROS Chemistry Products TIBC Kit	50 Tests
93	6844285	ORTHO 7% BSA	12 Bottles/ Box
94	8262487	VITROS Chemistry Products 7% BSA	12 Bottles/ Box
95	8559825	VITROS Chemistry Products Specialty Diluent	6 Bottles/ Box
96	1110352	VITROS Chemistry Products Urine Electrolyte Diluent	12 Bottles/ Box
97	8057812	VITROS Chemistry Products 950/FS Reference Fluid	30 Bottles/ Box
98	1765304	VITROS Chemistry Products 250/350 Reference Fluid	30 Bottles/ Box
99	1830033	VITROS Chemistry Products Immuno-Wash Fluid	30 Bottles/ Box
100	6844463	VITROS Chemistry Products Electrolyte Reference Fluid (ERF) 800	30 Bottles/ Box
101	6844464	VITROS Chemistry Products Electrolyte Reference Fluid (ERF) 300	30 Bottles/ Box
102	6801991	VITROS Chemistry Products AMPH Reagent	300 Tests
103	6801737	VITROS Chemistry Products ApoA1 Reagent	300 Tests
104	6801738	VITROS Chemistry Products ApoB Reagent	300 Tests
105	6802218	VITROS Chemistry Products ASO Reagent	300 Tests
106	6801988	VITROS Chemistry Products BARB Reagent	300 Tests
107	6801989	VITROS Chemistry Products BENZ Reagent	300 Tests
108	6801995	VITROS Chemistry Products COCM Reagent	300 Tests
109	6801735	VITROS Chemistry Products C3 Reagent	300 Tests
110	6801736	VITROS Chemistry Products C4 Reagent	300 Tests
111	6801728	VITROS Chemistry Products dLDL Reagent	600 Tests
112	6802001	VITROS Chemistry Products dTIBC Reagent	300 Tests
113	6801711	VITROS Chemistry Products GENT Reagent	300 Tests
114	6842956	VITROS Chemistry Products HCY 2 Reagent	300 Tests
115	6801739	VITROS Chemistry Products hsCRP Reagent	300 Tests
116	6801732	VITROS Chemistry Products IgA Reagent	300 Tests
117	6801733	VITROS Chemistry Products IgG Reagent	300 Tests
118	6801734	VITROS Chemistry Products IgM Reagent	300 Tests

Sr. No.	Product Code	Product Description	Pack Size
119	6801740	VITROS Chemistry Products mALB Reagent	300 Tests
120	6801996	VITROS Chemistry Products METD Reagent	300 Tests
121	6801997	VITROS Chemistry Products OP Reagent	300 Tests
122	6801741	VITROS Chemistry Products PALB Reagent	300 Tests
123	6801998	VITROS Chemistry Products PCP Reagent	300 Tests
124	6801729	VITROS Chemistry Products RF Reagent	300 Tests
125	6801994	VITROS Chemistry Products THC Reagent	300 Tests
126	6801712	VITROS Chemistry Products TOBRA Reagent	300 Tests
127	6801767	VITROS Chemistry Products TRFRN Reagent	300 Tests
128	6801710	VITROS Chemistry Products VALP Reagent	300 Tests
129	6801709	VITROS Chemistry Products VANC Reagent	300 Tests
130	6801713	VITROS Chemistry Products CAFFN Reagent Kit	200 Tests
131	6842905	VITROS Chemistry Products HbA1c Reagent Kit	300 Tests
132	6801873	VITROS Chemistry Products FS Calibrator 1	12 Bottles/ Box
133	6801696	VITROS Chemistry Products Calibrator Kit 11	6 bottles/ 1 Set/ Box
134	6801697	VITROS Chemistry Products Calibrator Kit 12	6 bottles/ 1 Set/ Box
135	6801698	VITROS Chemistry Products Calibrator Kit 13	6 bottles/ 1 Set/ Box
136	6801699	VITROS Chemistry Products Calibrator Kit 14	6 bottles/ 1 Set/ Box
137	6801700	VITROS Chemistry Products Calibrator Kit 16	5 bottles/ 1 Set/ Box
138	6801701	VITROS Chemistry Products Calibrator Kit 17	5 bottles/ 5 Sets/ Box
139	6801703	VITROS Chemistry Products Calibrator Kit 19	5 bottles/ 5 Sets/ Box
140	6801704	VITROS Chemistry Products Calibrator Kit 20	5 Bottles/ Box
141	6801705	VITROS Chemistry Products Calibrator Kit 21	5 bottles/ 1 Set/ Box
142	6801706	VITROS Chemistry Products Calibrator Kit 22	5 bottles/ 1 Set/ Box
143	6801707	VITROS Chemistry Products Calibrator Kit 23	5 bottles/ 1 Set/ Box
144	6801708	VITROS Chemistry Products Calibrator Kit 24	6 bottles/ 1 Set/ Box
145	6802304	VITROS Chemistry Products Calibrator Kit 26	1 Set/ Box
146	6802342	VITROS Chemistry Products Calibrator Kit 27	3 Sets/ Box

Sr. No.	Product Code	Product Description	Pack Size
147	6802323	VITROS Chemistry Products Calibrator Kit 28	1 Set/ Box
148	6802344	VITROS Chemistry Products Calibrator Kit 29	2 Sets/ Box
149	6802562	VITROS Chemistry Products Calibrator Kit 30	1 Bottle/ Box
150	6842906	VITROS Chemistry Products Calibrator Kit 31	3 Bottles/ Box
151	6801750	VITROS Chemistry Products %A1c Performance Verifier I	3 Bottles/ Box
152	6801751	VITROS Chemistry Products %A1c Performance Verifier II	3 Bottles/ Box
153	6801769	VITROS Chemistry Products ApoA1 Performance Verifier I	6 Bottles/ Box
154	6801770	VITROS Chemistry Products ApoB Performance Verifier I	6 Bottles/ Box
155	6802411	VITROS Chemistry Products ASO/RF Performance Verifier I	5 Bottles/ Box
156	6802412	VITROS Chemistry Products ASO/RF Performance Verifier II	5 Bottles/ Box
157	6802327	VITROS Chemistry Products DAT Performance Verifier I	6 Bottles/ Box
158	6802328	VITROS Chemistry Products DAT Performance Verifier II	6 Bottles/ Box
159	6802329	VITROS Chemistry Products DAT Performance Verifier III	6 Bottles/ Box
160	6802330	VITROS Chemistry Products DAT Performance Verifier IV	6 Bottles/ Box
161	6802331	VITROS Chemistry Products DAT Performance Verifier V	6 Bottles/ Box
162	6802348	VITROS Chemistry Products dTIBC Performance Verifier I	6 Vials/ Box
163	6802349	VITROS Chemistry Products dTIBC Performance Verifier II	6 Vials/ Box
164	6842957	VITROS Chemistry Products HCY 2 Performance Verifiers I, II & III	9 Bottles/ Box
165	6801742	VITROS Chemistry Products hsCRP Performance Verifier I	6 Bottles/ Box
166	6801888	VITROS Chemistry Products hsCRP Performance Verifier II	6 Bottles/ Box
167	6802049	VITROS Chemistry Products hsCRP Performance Verifier III	6 Bottles/ Box
168	6801746	VITROS Chemistry Products mALB Performance Verifier I	6 bottles/ Box
169	6801747	VITROS Chemistry Products mALB Performance Verifier II	6 bottles/ Box
170	6801771	VITROS Chemistry Products PALB Performance Verifier I	6 bottles/ Box
171	6801772	VITROS Chemistry Products PALB Performance Verifier II	6 bottles/ Box
172	6801744	VITROS Chemistry Products Protein Performance Verifier I	6 bottles/ Box
173	6801745	VITROS Chemistry Products Protein Performance Verifier II	6 bottles/ Box
174	6801768	VITROS Chemistry Products Protein Performance Verifier III	6 bottles/ Box
175	6801874	VITROS Chemistry Products FS Reconstitution Diluent	12 Bottles/ Box
176	6801752	VITROS Chemistry Products FS Diluent Pack 1(Apo Diluent/UED)	3 Packs/ Box
177	6801753	VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline)	3 Packs/ Box

Sr. No.	Product Code	Product Description	Pack Size
178	6801754	VITROS Chemistry Products FS Diluent Pack 3(Specialty Diluent/Water)	3 Packs/ Box
179	6802326	VITROS Chemistry Products FS Diluent Pack 4(DAT Diluent/DAT Diluent 2)	6 Packs/ Box
180	6802214	VITROS Chemistry Products HPT Reagent	300 Tests
181	6802311	VITROS Chemistry Products AAT/HPT Performance Verifier I	6 bottles/ Box
182	6802216	VITROS Chemistry Products AAT Reagent	300 Tests
183	6802312	VITROS Chemistry Products AAT/HPT Performance Verifier II	6 bottles/ Box
184	6802313	VITROS Chemistry Products AAT/HPT Performance Verifier III	6 bottles/ Box
185	6802310	VITROS Chemistry Products Calibrator Kit 99	1 Set/ Box
186	6844508	VITROS Chemistry Products Calibrator Kit 32	3 Sets/ Box
187	8221384	VITROS Chemistry Products PHBR Slides	90 Test
188	6844520	VITROS Chemistry Products A1c Slides	250 Test
189	6922333	VITROS Chemistry Products wrCRP Reagent	300 Tests
190	6844521	VITROS Chemistry Products Calibrator Kit 33	4 vials each of calibrator 1, 2, and 3
191	6907789	VITROS Chemistry Products Calibrator kit 34	6 vials X 2 mL

Authorized Signatory

Ana Parra
(APARRA)

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Ana Parra
Sr. Associate, International Regulatory Affairs

To Whom So Ever It May Concern

Date: 08 March 2022

Proprietary Article Certificate

We, Ortho-Clinical Diagnostics Inc., USA, located at 100 Indigo Creek Drive, Rochester, NY 14626 the legal manufacturer having facilities NPA de Mexico S. de R.L de C.V., Sor Juana Ines de la Cruz# 20150 Interior 5, Cd., Industrial Tijuana Baja California, MEXICO 22444.

Hereby confirm that one of the above facilities is designated as the official manufacturer of record for the VITROS® 5600 Integrated System. Details listed in below table.

We confirm that we have control over the manufacturer of our system and hold a product License and trademark and other intellectual property rights for the technology and hardware in the VITROS® 5600 Integrated System

Product Code	Product Description
6802413	VITROS® 5600 Integrated System

VITROS® 5600 Integrated System offers five proprietary technologies:

- VITROS® MicroSlide Technology** offers an entire integrated test environment on a thin piece of film. Spreading, masking, scavenger, and reagent layers are discretely combined on one postage-stamp-sized slide to produce first-class precision and accuracy. When plasma, serum, urine, or cerebrospinal fluid come into contact with these dry chemical layers, a spectral reaction occurs, which can be measured by the system. This layered dry slide technology enables separate reaction domains—maximizing each step for exceptional assay performance.
- VITROS® MicroTip Technology** utilizes single-use disposable tips and closed reagent packs to eliminate the risk of sample carryover and reagent-to-reagent contamination, and to extend onboard reagent stability. It requires no drains, plumbing, fixed probes, or mixing assemblies to perform therapeutic and abused drug testing, specific proteins, and user-defined applications.

3. **VITROS® MicroWell Technology**, which maximizes binding capacities with a unique coating process. Enhanced Chemiluminesce Detection Technology is a component of MicroWell Technology that provides wide dynamic ranges and exceptional immunoassay precision and accuracy across multiple disease states.
4. **VITROS® Microsensor Technology**, which utilizes the VITROS MicroSensor™ system to perform automated semi-quantitative sample quality index determinations on serum, plasma, and cerebrospinal fluid samples. The MicroSensor™ feature is intended to assist laboratory personnel in assessing the suitability of a patient sample for use on the VITROS 5600 Integrated System. The optical absorbance from 400-800 nm is automatically read and recorded for each sample. Multi-variant analysis of the spectral data provides estimates of the hemolysis, icterus, and turbidity indices in the sample.
5. **VITROS® Intellicheck® Technology**, which is Integrated Process Control, and offers unique technologies that perform, monitor, and verify diagnostic checks throughout sample processing, assay processing, and reporting results. IntelliReport™, a component of Intellicheck® Technology, reports real-time status of every result, assures the integrity of every result, and serves as an important record for result quality.

Ana Parra
(APARRA)

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Ana Parra (APARRA)
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Date: 2022.03.08
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Ana Parra
Associate, International Regulatory Affairs

8-March-2022
Date

Date: 10 July 2023

Proprietary Certificate

TO WHOMSOEVER IT MAY CONCERN

Ortho Clinical Diagnostics, Inc., USA is a legal manufacturer of clinical diagnostics equipment VITROS ECi/ECiQ Immunodiagnostic System/ VITROS 3600 Immunodiagnostic System/ VITROS 5600 Integrated System/ VITROS XT 7600 Integrated System & is proprietary product of Ortho-Clinical Diagnostics, Inc., USA and is exclusively marketed in India by Ortho Clinical Diagnostics India Pvt. Ltd. having its Registered office at 403, Leela Business Park , Andheri Kurla Road , Andheri East , Mumbai -400059, India.

Below products are proprietary product of Ortho Clinical Diagnostics with manufacturer Ortho Clinical Diagnostics, UK or Ortho Clinical Diagnostics, USA (indicated by *) and can only be used on VITROS ECi/ECiQ Immunodiagnostic System/ VITROS 3600 Immunodiagnostic System/ VITROS 5600 Integrated System/ VITROS XT 7600 Integrated System & no other products can be used on these instrument systems.

Sr. No.	Product Code	Product Description	Pack Size
Reagents			
1	6199922	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	100 wells
2	6199919	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	100 wells
3	6905558	VITROS Immunodiagnostic Products B•R•A•H•M•S PCT Reagent Pack	100 wells
4	6844436	VITROS Immunodiagnostic Products hs Troponin I Reagent Pack	100 Tests
5	1453489	VITROS Immunodiagnostic Products B12 Reagent Pack	100 wells
6	1142561	VITROS Immunodiagnostic Products B12/Folate Reagent Pack 3	200 wells
7	8356636	VITROS Immunodiagnostic Products Ferritin Reagent Pack	100 wells
8	1513266	VITROS Immunodiagnostic Products Folate Reagent Pack	100 wells
9	1896836	VITROS Immunodiagnostic Products CK-MB Reagent Pack	100 wells
10	6801042	VITROS Immunodiagnostic Products Myoglobin Reagent Pack	100 wells
11	6802301	VITROS Immunodiagnostic Products Troponin I ES Reagent Pack	100 wells
12	6801827	VITROS Immunodiagnostic Products CMV IgG Reagent Pack	100 wells
13	6801830	VITROS Immunodiagnostic Products CMV IgM Reagent Pack	100 wells

Sr. No.	Product Code	Product Description	Pack Size
14	1074053	VITROS Immunodiagnostic Products Cortisol Reagent Pack	100 wells
15	1315589	VITROS Immunodiagnostic Products Free T3 Reagent Pack	100 wells
16	1387000	VITROS Immunodiagnostic Products Free T4 Reagent Pack	100 wells
17	8450124	VITROS Immunodiagnostic Products Anti-HAV IgM Reagent Pack	100 Tests
18	6801461	VITROS Immunodiagnostic Products Anti-HAV Total Reagent Pack	100 Tests
19	6802892	VITROS Immunodiagnostic Products Intact PTH Reagent Pack	100 wells
20	6802156	VITROS Immunodiagnostic Products NT-proBNP Reagent Pack	100 wells
21	6800030	VITROS Immunodiagnostic Products NTx Reagent Pack	100 wells
22	1920115	VITROS Immunodiagnostic Products CEA Reagent Pack	100 Wells
23	6800038	VITROS Immunodiagnostic Products CA 125 II Reagent Pack	100 wells
24	6800039	VITROS Immunodiagnostic Products CA 15-3 Reagent Pack	100 wells
25	6800040	VITROS Immunodiagnostic Products CA 19-9 Reagent Pack	100 Wells
26	6842845	VITROS Immunodiagnostic Products Free PSA Reagent Pack	100 wells
27	6842844	VITROS Immunodiagnostic Products Total PSA II Reagent Pack	100 wells
28	1925551	VITROS Immunodiagnostic Products AFP Reagent Pack	100 wells
29	8552630	VITROS Immunodiagnostic Products Estradiol Reagent Pack	100 wells
30	1931922	VITROS Immunodiagnostic Products FSH Reagent Pack	100 wells
31	1350198	VITROS Immunodiagnostic Products LH Reagent Pack	100 wells
32	1938570	VITROS Immunodiagnostic Products Progesterone Reagent Pack	100 wells
33	1849793	VITROS Immunodiagnostic Products Prolactin Reagent Pack	100 wells
34	1435205	VITROS Immunodiagnostic Products Testosterone Reagent Pack	100 wells
35	6802220	VITROS Immunodiagnostic Products Total β-hCG II Reagent Pack	100 wells
36	1484427	VITROS Immunodiagnostic Products Rubella IgM Reagent Pack	100 wells

Sr. No.	Product Code	Product Description	Pack Size
37	8536195	VITROS Immunodiagnostic Products Rubella IgG Reagent Pack	100 wells
38	6842803	VITROS Immunodiagnostic Products Syphilis TPA Reagent Pack	100 wells
39	1322528	VITROS Immunodiagnostic Products Total T3 Reagent Pack	100 wells
40	8744468	VITROS Immunodiagnostic Products Total T4 Reagent Pack	100 wells
41	1912997	VITROS Immunodiagnostic Products TSH Reagent Pack	100 wells
42	8091399	VITROS Immunodiagnostic Products Toxoplasma IgG Reagent Pack	100 wells
43	8669335	VITROS Immunodiagnostic Products Toxoplasma IgM Reagent Pack	100 wells
44	6842894	VITROS Immunodiagnostic Products 25-OH Vitamin D Reagent Pack	100 wells
45	1471481	VITROS Immunodiagnostic Products T3 Uptake Reagent Pack	100 Tests
46	1107804	VITROS Immunodiagnostic Products Red Cell Folate Pack	50 Tests
47	6844411	VITROS Immunodiagnostic Products NephroCheck Test Reagent Pack	100 Tests
48	6844425	VITROS Immunodiagnostic Products Insulin Reagent Pack	100 Tests
49	8496812	VITROS Immunodiagnostic Products Anti-HBc Reagent Pack	100 wells
50	8577413	VITROS Immunodiagnostic Products Anti-HBc IgM Reagent Pack	100 wells
51	8864860	VITROS Immunodiagnostic Products Anti-HBe Reagent Pack	100 wells
52	8211880	VITROS Immunodiagnostic Products HBeAg Reagent Pack	100 wells
53	1787753	VITROS Immunodiagnostic Products Anti-HBs Reagent Pack	100 wells
54	6802131	VITROS Immunodiagnostic Products HBsAg ES Reagent Pack	100 Tests
55	6802133	VITROS Immunodiagnostic Products HBsAg ES Confirmatory Kit	100 wells
56	1318450	VITROS Immunodiagnostic Products Anti-HCV Reagent Pack	100 wells
57	1241850	VITROS Immunodiagnostic Products Anti-HIV 1 + 2 Reagent Pack	100 Tests
58	6842779	VITROS Immunodiagnostic Products HIV Combo Reagent Pack	100 wells

Sr. No.	Product Code	Product Description	Pack Size
59	6844423	VITROS Immunodiagnostic Products C-peptide Reagent Pack	100 Tests
60	6844452	VITROS Immunodiagnostic Products NT-proBNP II Reagent Pack	100 Tests
61	6900446	VITROS Immunodiagnostic Products Anti-HTLV I/II Reagent Pack	100 Test
62	6199971	VITROS Immunodiagnostic Products IL 6 Reagent	100 Test
Calibrator			
Sr. No.	Product Code	Product Description	Pack Size
63	6199923	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator	2 x 1ml
64	6199920	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Calibrator	2 x 1ml
65	6905559	VITROS Immunodiagnostic Products B•R•A•H•M•S PCT Calibrators	2 levels/1 ml vials
66	6844437	VITROS Immunodiagnostic Products hs Troponin I Calibrator	3 vials (1 per level)
67	1540525	VITROS Immunodiagnostic Products B12 Calibrators	3 levels/1set
68	1158864	VITROS Immunodiagnostic Products Ferritin Calibrators	3 levels/3 sets freeze dried
69	1311075	VITROS Immunodiagnostic Products Folate Calibrators	3 levels/1set Liquid
70	1286293	VITROS Immunodiagnostic Products CK-MB Calibrators	3 levels/3 sets freeze dried
71	6801043	VITROS Immunodiagnostic Products Myoglobin Calibrators	3 levels/1set
72	6802302	VITROS Immunodiagnostic Products Troponin I ES Calibrators	3levels/1set
73	619 9923	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator	1 Box- 2x 1 ml
74	619 9920	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Calibrator	1 Box- 2x 1 ml
75	6801828	VITROS Immunodiagnostic Products CMV IgG Calibrators	2 levels, 1 vial each
76	6801831	VITROS Immunodiagnostic Products CMV IgM Calibrator	1 level
77	1681543	VITROS Immunodiagnostic Products Cortisol Calibrators	3 levels/3 sets freeze dried
78	1112820	VITROS Immunodiagnostic Products Free T3 Calibrators	3 levels/3 sets freeze dried

Sr. No.	Product Code	Product Description	Pack Size
79	1728872	VITROS Immunodiagnostic Products Free T4 Calibrators	3 levels/3 sets freeze dried
80	1372101	VITROS Immunodiagnostic Products Anti-HAV IgM Calibrator	1 level/1 set liquid
81	1421932	VITROS Immunodiagnostic Products HBsAg Calibrators	1 level/ 1 set
82	6801462	VITROS Immunodiagnostic Products Anti-HAV Total Calibrator	1 vial
83	6802893	VITROS Immunodiagnostic Products Intact PTH Calibrators	3 levels/1 set
84	6802157	VITROS Immunodiagnostic Products NT-proBNP Calibrators	3 levels/1 set
85	6800031	VITROS Immunodiagnostic Products NTx Calibrators	3levels/1 set Liquid
86	6800034	VITROS Immunodiagnostic Products CA 125 II Calibrators	3levels/1 set Liquid
87	6800033	VITROS Immunodiagnostic Products CA 15-3 Calibrators	3 levels/1 set Liquid
88	6800035	VITROS Immunodiagnostic Products CA 19-9 Calibrators	3 levels/1 set Liquid
89	1062306	VITROS Immunodiagnostic Products CEA Calibrators	3 levels/1 set Liquid
90	6842847	VITROS Immunodiagnostic Products Free PSA Calibrators	3 levels/1 set Liquid
91	6842849	VITROS Immunodiagnostic Products Total PSA II Calibrators	3 levels/1 set Liquid
92	1515154	VITROS Immunodiagnostic Products AFP Calibrators	3 levels/1 set liquid
93	1318930	VITROS Immunodiagnostic Products Estradiol Calibrators	3 levels/1 set freeze dried
94	1901263	VITROS Immunodiagnostic Products FSH Calibrators	2 levels/1 set liquid
95	1090133	VITROS Immunodiagnostic Products LH Calibrators	2 levels/1 set liquid
96	8254898	VITROS Immunodiagnostic Products Progesterone Calibrators	3 sets of 3 Calibrators
97	1113596	VITROS Immunodiagnostic Products Prolactin Calibrators	2 levels/3 sets freeze dried
98	1306026	VITROS Immunodiagnostic Products Testosterone Calibrators	3 levels/1 set liquid
99	6802221	VITROS Immunodiagnostic Products Total β -hCG II Calibrators	2 levels/3 sets freeze dried
100	8017600	VITROS Immunodiagnostic Products Rubella IgM Calibrator	1 level

Sr. No.	Product Code	Product Description	Pack Size
101	8209074	VITROS Immunodiagnostic Products Rubella IgG Calibrators	3 levels, 1 vial each
102	6842804	VITROS Immunodiagnostic Products Syphilis TPA Calibrator	1 level/ 1 set
103	1614965	VITROS Immunodiagnostic Products Total T3 Calibrators	3 levels/I set liquid
104	1393396	VITROS Immunodiagnostic Products Total T4 Calibrators	3 levels/I set liquid
105	1487289	VITROS Immunodiagnostic Products TSH Calibrators	3 levels/1 set liquid
106	8254989	VITROS Immunodiagnostic Products Progesterone Calibrators	2levels/1set liquid
107	1893312	VITROS Immunodiagnostic Products Toxoplasma IgG Calibrators	2 levels, 1 vial each
107	1120492	VITROS Immunodiagnostic Products Toxoplasma IgM Calibrator	1 level
109	6842893	VITROS Immunodiagnostic Products 25-OH Vitamin D Calibrators	3 levels/1 set
110	1209733	VITROS Immunodiagnostic Products T3 Uptake Calibrators	3 sets of each of 2 vials
111	6844412	VITROS Immunodiagnostic Products NephroCheck Test Calibrator	9 vials (3 per level)
112	6844426	VITROS Immunodiagnostic Products Insulin Calibrator	3 vials (1 per level)
113	1256494	VITROS Immunodiagnostic Products Anti-HBc Calibrator	1 level/1 set liquid
114	1100387	VITROS Immunodiagnostic Products Anti-HBc IgM Calibrator	1 level/1 set liquid
115	1523984	VITROS Immunodiagnostic Products Anti-HBe Calibrator	3 levels/3 sets liquid
116	1914498	VITROS Immunodiagnostic Products HBeAg Calibrator	3 levels/3 sets liquid
117	1524693	VITROS Immunodiagnostic Products Anti-HBs Calibrators	3 vials (1 per level)
118	6802132	VITROS Immunodiagnostic Products HBsAg ES Calibrator	1 vial
119	1940667	VITROS Immunodiagnostic Products Anti-HCV Calibrator	1 level/ 1 set
120	1700863	VITROS Immunodiagnostic Products Anti-HIV 1 + 2 Calibrator	1 vial
121	6842780	VITROS Immunodiagnostic Products HIV Combo Calibrator	1 vial

Sr. No.	Product Code	Product Description	Pack Size
122	6844424	VITROS Immunodiagnostic Products C-peptide Calibrators	9 vials (3 per level)
123	6844453	VITROS Immunodiagnostic Products NT-proBNP II Calibrators	3 vials (1 per level)
124	6900448	VITROS Immunodiagnostic Products Anti-HTLV I/II Calibrator	1 vial (1 per level)
125	6199972	VITROS Immunodiagnostic Products VITROS IL-6 Calibrator	2 levels/ 3 sets
Controls			
Sr. No.	Product Code	Product Description	Pack Size
126	6199924	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Controls	1 Box-3x2 X 2 ml
127	6199921	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Controls	1 Box-3x2 X2 ml
128	6905560	VITROS Immunodiagnostic Products B•R•A•H•M•S PCT Controls	3 levels / 1 ml vials
129	6900040	VITROS Immunodiagnostic Products hs Troponin I Low Control	3 vials
130	1619360	VITROS Immunodiagnostic Products Anemia Controls	3 Sets/ Pack
131	1420025	VITROS Immunodiagnostic Products Metabolism Controls	3 Sets/ Pack
132	1315654	VITROS Immunodiagnostic Products Free Thyroid Controls	3 Sets/ Pack
133	6800835	VITROS Immunodiagnostic Products Anti-HAV IgM Controls	3 Sets/ Pack
134	6801463	VITROS Immunodiagnostic Products Anti-HAV Total Controls	3 Sets/ Pack
135	6802895	VITROS Immunodiagnostic Products Intact PTH Controls	3 Sets/ Pack
136	6800336	VITROS Immunodiagnostic Products NTx Controls	3 Sets/ Pack
137	1009406	VITROS Immunodiagnostic Products RE Controls	3 Sets/ Pack
138	6800660	VITROS Immunodiagnostic Products Testosterone Controls	3 Sets/ Pack
139	6842805	VITROS Immunodiagnostic Products Syphilis TPA Controls	3 sets of 2 vials/ Pack
140	1410646	VITROS Immunodiagnostic Products Total Thyroid Controls	3 Sets/ Pack
141	6844413	VITROS Immunodiagnostic Products NephroCheck Test Controls	3 sets of freeze-dried Controls 1, 2, and 3

Sr. No.	Product Code	Product Description	Pack Size
142	6800836	VITROS Immunodiagnostic Products Anti-HBc Controls	3 Sets/ Pack
143	6800834	VITROS Immunodiagnostic Products Anti-HBc IgM Controls	3 Sets/ Pack
144	6800837	VITROS Immunodiagnostic Products Anti HBe Controls	3 Sets/ Pack
145	6800389	VITROS Immunodiagnostic Products Anti-HBs Controls	3 Sets/ Pack
146	6800598	VITROS Immunodiagnostic Products HBsAg Controls	2 levels/ 3 sets
147	6800731	VITROS Immunodiagnostic Products Anti-HCV Controls	2 levels/ 3 sets
148	6800586	VITROS Immunodiagnostic Products Anti-HIV 1 + 2 Controls	3 levels/ 3 sets
149	6844507	VITROS Immunodiagnostic Products NT-proBNP II Control	3 vials
150	6842905	VITROS Immunodiagnostic Products Syphilis TPA Control	2 levels
151*	91474	Liquid QC Cardiac Marker Control VS	2 X 3 X 3 ml
152*	10820	Tumor marker control	Control level 1 - 3 X 3 ml Control level 2 - 3 X 3 ml (Control Level 3 X 3 ml)
153	6900449	VITROS Immunodiagnostic Products Anti-HTLV I/II Controls	3 sets of each control
154	6199973	VITROS IL-6 Controls	2 levels/ 3 sets

Consumables			
155	1072693	VITROS Immunodiagnostic Products Signal Reagent	2 x 200 T
156	8389793	VITROS Immunodiagnostic Products Universal Wash Reagent	2 x 5 L
157	1831312	VITROS Immunodiagnostic Products Maintenance Pack	2 Packs
158	8430373	VITROS Immunodiagnostic Products High Sample Diluent A Reagent Pack	100 wells
159	8321200	VITROS Immunodiagnostic Products High Sample Diluent B Reagent Pack	100 wells
160	8642712	VITROS Immunodiagnostic Products High Sample Diluent A	4 bottles x 27ml
161	1435866	VITROS Immunodiagnostic Products High Sample Diluent B	4 bottles x 27ml
162	1877158	VITROS Immunodiagnostic Products System Cleaning Solution	2 x 1 litre bottles

Note: * Manufactured by Ortho Clinical Diagnostic's contract manufacturer.

Authorized Signatory

Ana Parra
(APARRA)

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Ana Parra
Sr. Associate, International Regulatory Affairs

ANNEXURE – I

SPECIFICATIONS

Objection should be submitted in following format:

S. no	Item specification as given	Specification offered by firm	Deviation if any	Remarks