

TRANSASIA BIOMEDICALS LIMITED

IQQPQ HS Pathology Pvt.Ltd,Changarh

Instrument Name

EM200

Instrument SN

V200403

**TRANSASIA**  
Bio-Medicals Ltd.

## INSTALLATION QUALIFICATION

| S. No | Title   |
|-------|---|
| 1     | Pre Approval  |
| 2     | Objective   |
| 3     | Scope   |
| 4     | Instrument description                                      |
| 5     | Identification of Major components / accessories            |
| 6     | Installation check / review                                 |
| 7     | Inspection check / review                                   |
| 8     | Identification and verification of material of construction |
| 9     | Identification and verification of supporting utilities     |
| 10    | Identification of standard operating procedure              |
| 11    | Abbreviations   |
| 12    | Post Approval   |





|   |              |                      |                |
|---|--------------|----------------------|----------------|
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| <b>Instrument Name</b>                      | <b>EM200</b> | <b>Instrument SN</b> | <b>V200403</b> |

## 2.0 OBJECTIVE

The objective of this document is to provide an outline for the inspection of EM 200 (Bio- Chemistry Random Analyzer) and to verify that the following boundaries:

- o Each Installed subcomponent complies with the engineering design and instrument data sheet / design specifications & manufacturer's recommendations.
- o To ensure that all the safety features are defined before the start up of operational qualification exercise.
- o The system meets the current regulatory requirements.
- o To identify the Standard operating procedures for Operational Qualification.

## 3.0 SCOPE

The scope of this protocol is to outline procedure for Installation qualification of the subjected instrument within the following boundaries:

- o Identification and verification of its Major components / Accessories
- o Identification, Classification and Verification of Process Control Instruments / Gauges / Devices
- o Identification and verification of Material of Construction
- o Identification and verification of Supporting Utilities
- o Identification of Standard Operating Procedures
- o Identification and Verification of Documents



|                                      |       |               |   |
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| Instrument Name                      | EM200 | Instrument SN | V200403                                     |

#### 4.0 INSTRUMENT DESCRIPTION

The Clinical Chemistry Analyzer is an open, full automated, discrete, patient prioritized, random access, computerized analyzer.

#### Technical Specifications:

|                          |  |
|--------------------------|--|
| System Type              | Open, Automated, Discrete, Random Access, Patient Prioritized, 1/2 Reagents                  |
| Analysis Speed           | 200 Biochemistry tests per hour 400 tests per hour (with ISE) for a cycle time of 18 seconds |
| Display resolution       | 1024 X 768   |
| Analyzer Dimensions      | 810 (W) x 800 (D) x 600 (H) mm   |
| Number of tests on board | Maximum: 50  |
| Assay Modes              | 1-point, 2-point, Rate-A and Rate -B, ISE optional   |
| Calibration              | Linear (two point and multi point), Factorized and Non-linear multipoint                     |
| Sample (Tubes / Cups)    | Primary tubes of 5, 7 or 10mL & sample cups  |
| Photometric Optics       | Mono and Bi-chromatic measurement using 8 wavelengths  |
| Absorbance Range         | 0 – 2.5  |
| Auxiliary Data           | 10,000 results   |
| Interface                | RS-232 C port for Bi-directional Communication   |
| Stat Sampling            | Total 30 positions   |



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**Purpose:**

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, Cholestrol, Tri-glycerides, Proteins, etc.

The working unit of the analyzer comprises the following:

- Basic operating unit with an intelligent photometer
- Sophisticated robotics combined with an operating console and a central processing unit(CPU).

**Operating Unit:**

The operating unit of the analyzer includes the sample and reagent handling systems. The sample handling system consists of a sample tray, sample arm, sample syringe and a wash station for the sample probe.

**Photometric System:**

The photometric system consists of 45 hard glass cuvettes, multi wavelength diffracting photometer and a halogen lamp.

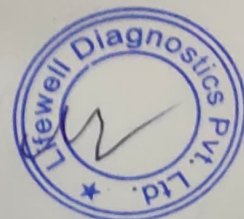
**Operating Console:**

The operating console consists of a touch screen (optional) color TFT monitor, a key board and a mouse.

**CPU (Central Processing Unit):**

CPU consists of Pentium – IV 1.7 GHz processor (or Higher) with a 48 x CD Drive, and minimum 256 MB memory. The application software can be installed on computers with operating systems of Windows XP.

Besides the above mentioned, this analyzer has got the unique Software and Hardware features.



Instrument Name

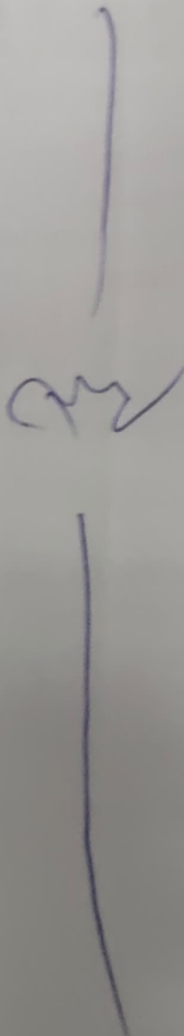
EM200

Instrument SN

V200403

## 5.0 IDENTIFICATION OF MAJOR COMPONENTS /ACCESSORIES

Details of each major component identified in this section, is recorded in a data sheet.

| Name of Component / Accessories | Present  | Verified by Signature   | Observations |
|---------------------------------|----------|---|--------------|
|                                 | Yes / No |   |              |
| Sample Tray / Disk              | Yes      |  | OK           |
| Sample Syringe                  | Yes      |   |              |
| Sample Probe                    | Yes      |   |              |
| Wash Station for Sample Probe   | Yes      |   |              |
| Reagent Tray / Disk             | Yes      |   |              |
| Reagent Bottles                 | Yes      |   |              |
| Reagent Probe                   | Yes      |   |              |
| Stirrer                         | Yes      |   |              |
| Permanent Reaction Cuvette      | Yes      |   |              |
| 9 Stage Laundry System          | Yes      |   |              |
| Light Source                    | Yes      |   |              |
| Sample Cups                     | Yes      |   |              |
| Software of EM 200              | Yes      |   |              |
|                                 |          |   |              |



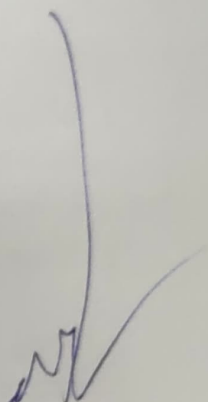
Instrument Name

EM200


Instrument SN

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## 6.0 INSTALLATION CHECK /REVIEW

| S. No. | Statement  | Yes / No | Verified by<br>Signature  |
|--------|--|----------|---|
| 1.     | Verify that the "as built" drawings are complete and represent the design concept              | Yes      |  |
| 2.     | Verify that major components / accessories are securely anchored and shock proof.              | Yes      |   |
| 3.     | Verify that there is no observable physical damage.  | Yes      |   |
| 4.     | Verify that there is sufficient room of servicing provided                                     | Yes      |   |
| 5.     | Verify that all utilities and electrical connections have been done according to the drawings. | Yes      |   |
| 6.     | Walking access to ground mounted instrument provided.  | Yes      |   |
| 7.     | Required electric connections are tight, weather proof and earthed.                            | Yes      |   |
| 8.     | Instrument identification nameplate visible.   | Yes      |   |
| 9.     | Units installed on foundation and secure in place as per manufacturer's recommendations.       | Yes      |   |
| 10.    | Verify that the instruments installed and leveled properly on the floor.                       | Yes      |   |
| 11.    | Verify that the Material of Construction is proper and meeting the requirements.               | Yes      |   |



|                                      |       |               |  |
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| Instrument Name                      | EM200 | Instrument SN |  |

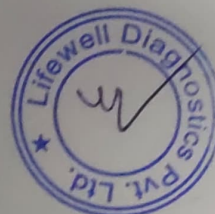
## 7.0 INSPECTION CHECK / REVIEW

### Instructions for completing the check / review

1. For each **data sheet**, record the required information with pen. Wherever required record "Yes" for acceptance, "No" for non-compliance and "NA" for not applicable.

**"No" replies must be explained / justified.**

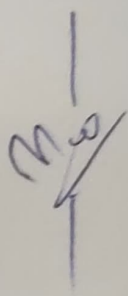
2. When more than one component of same specification/type exists in the same equipment, individual data sheets should be filled for each component.
3. When a list of acceptable options is presented, tick (b) the option that is actually present.
4. In the "**Method of Verification**" column indicate that item is installed and inspected, according to manufacturer's specifications, such as by Visual / Physical, SOP, Test Certificate, Manual, etc.



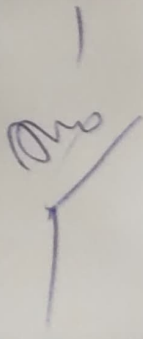


|                 |       |               |         |
|-----------------|-------|---------------|---------|
| Instrument Name | EM200 | Instrument SN | V200403 |
|-----------------|-------|---------------|---------|


Instrument/ Component Name: Sample Tray / Disk

| Description                   | Specified                          | Actual | Method of Verification | Verified by Signature   |
|-------------------------------|------------------------------------|--------|------------------------|---|
| No. of patient cups / samples | 30 positions                       | OK     | Physical/Practical     |  |
| Standards / Stat              | 30 positions                       | OK     | Physical/Practical     |   |
| Blank                         | Can be put on any position         | OK     | Physical/Practical     |   |
| Controls                      | Can be programmed on any positions | OK     | Physical/Practical     |   |

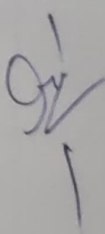
Instrument/ Component Name: Sample Syringe

| Description                   | Specified                               | Actual | Method of Verification | Verified by Signature   |
|-------------------------------|---|--------|------------------------|---|
| Dispensing Volume             | 2 – 70 $\mu$ L                          | OK     | Physical/Practical     |  |
| Installed Location            | Behind the instrument on the right side | OK     | Physical/Practical     |   |
| Quantity                      | 01 No.                                  | OK     | Physical/Practical     |   |
| Increase in dispensing volume | 0.2 $\mu$ L                             | OK     | Physical/Practical     |   |

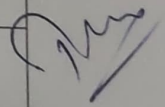


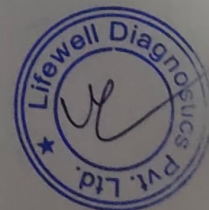
|                                      |       |               |         |  |
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| Instrument Name                      | EM200 | Instrument SN | V200403 |  |

**Instrument/ Component Name: Sample Probe**

| Description                   | Specified      | Actual | Method of Verification | Verified by Signature   |
|-------------------------------|----------------|--------|------------------------|---|
| Aspiration Volume             | 2 – 70 $\mu$ L | OK     | Physical/Practical     |  |
| MOC                           | Teflon coated  | OK     | Physical/Practical     |   |
| Quantity                      | 01 No.         | OK     | Physical/Practical     |   |
| Increase in aspiration volume | 0.2 $\mu$ L    | OK     | Physical/Practical     |   |

**Instrument/ Component Name: Wash Station for Sample Probe**

| Description       | Specified              | Actual | Method of Verification | Verified by Signature   |
|-------------------|------------------------|--------|------------------------|---|
| No. of position   | 01 No                  | OK     | Physical/Practical     |  |
| Type of positions | i) Drain<br>ii) Trough | OK     | Physical/Practical     |   |



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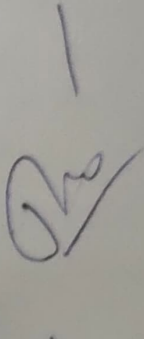
Instrument Name

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Instrument SN

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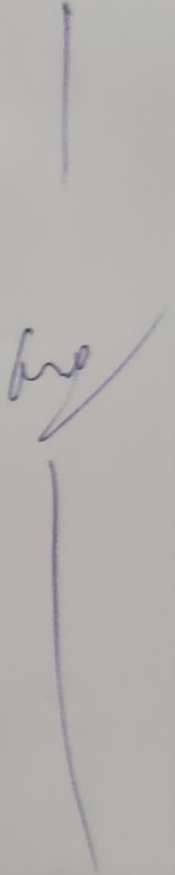
Instrument/ Component Name: Reagent Tray / Disk

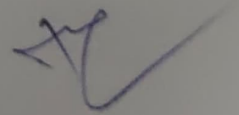
| Description                      | Specified         | Actual | Method of Verification | Verified by Signature   |
|----------------------------------|-------------------|--------|------------------------|---|
| Cool reagent disk                | 50 positions      | OK     | Physical/Practical     |  |
| Outer Rings                      | 25 positions      | OK     | Physical/Practical     |   |
| Inner Rings                      | 25 positions      | OK     | Physical/Practical     |   |
| Adaptors of 5mL                  | 50 positions      | OK     | Physical/Practical     |   |
| Maintenance of Temperature       | 8-12°C ± 2°C      | OK     | Physical/Practical     |   |
| Rotation of disk                 | Counter-Clockwise | OK     | Physical/Practical     |   |
| Time for Rotation of one Cuvette | Every 18 seconds  | OK     | Physical/Practical     |   |



|                                      |       |               |         |  |
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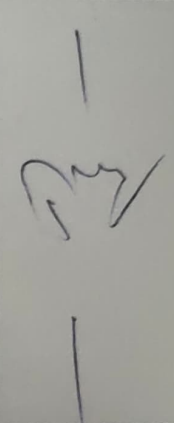
**Instrument/ Component Name: Reagent Bottles**

| Description                | Specified                                | Actual | Method of Verification | Verified by Signature  |
|----------------------------|--|--------|------------------------|--|
| Minimum Capacity           | 20 mL                                    | OK     | Physical/Practical     |  |
| Maximum Capacity           | 50 mL                                    | OK     | Physical/Practical     |  |
| Quantity (Large)           | 25 Nos'                                  | OK     | Physical/Practical     |  |
| Quantity (Smaller)         | 25 Nos'                                  | OK     | Physical/Practical     |  |
| Type                       | Screw Capped                             | OK     | Physical/Practical     |  |
| Outer ring position        | 20 mL bottles & 5ml adaptors             | OK     | Physical/Practical     |  |
| Inner ring position        | 20 mL & 50 mL bottles & 5ml adaptors     | OK     | Physical/Practical     |  |
| MOC                        | Plastic                                  | OK     | Physical/Practical     |  |
| Adaptor                    | 50 Nos'                                  | OK     | Physical/Practical     |  |
| Adaptor Capacity           | 5 mL                                     | OK     | Physical/Practical     |  |
| Identification of Reagents | Barcode labels on the reagent containers | OK     | Physical/Practical     |  |

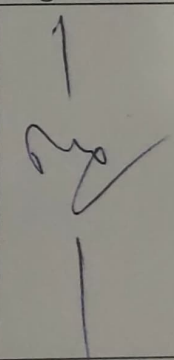


|   |              |                      |                |   |
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| <b>Instrument Name</b>                      | <b>EM200</b> | <b>Instrument SN</b> | <b>V200403</b> |   |

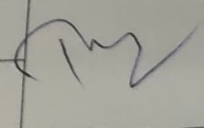
**Instrument/ Component Name: Reagent Probe**

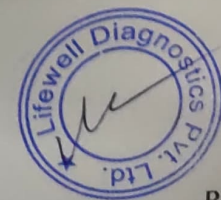
| Description                              | Specified                 | Actual | Method of Verification | Verified by Signature   |
|--|---------------------------|--------|------------------------|---|
| Aspiration/Dispensing Volume             | R1: 50 – 300 $\mu$ L      | OK     | Physical/Practical     |  |
|  | R2: 0 or 10 – 300 $\mu$ L | OK     | Physical/Practical     |   |
| MOC                                      | Teflon coated             | OK     | Physical/Practical     |   |
| Quantity                                 | 02 Nos'.                  | OK     | Physical/Practical     |   |
| Increase in aspiration/dispensing volume | 1 $\mu$ L                 | OK     | Physical/Practical     |   |

**Instrument/ Component Name: Reagent Syringe**

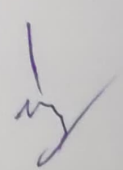
| Description                   | Specified                                       | Actual | Method of Verification | Verified by Signature  |
|-------------------------------|---|--------|------------------------|--|
| Maximum capacity              | 500 $\mu$ L                                     | OK     | Physical/Practical     |  |
| Installed Location            | At the back of the instrument on the right side | OK     | Physical/Practical     |  |
| Quantity                      | 01 No. —  | OK     | Physical/Practical     |  |
| Increase in dispensing volume | 1 $\mu$ L                                       | OK     | Physical/Practical     |  |

**Instrument/ Component Name: Stirrer**

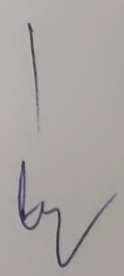
| Description    | Specified      | Actual | Method of Verification | Verified by Signature   |
|----------------|----------------|--------|------------------------|---|
| Type           | Single Stirrer | OK     | Physical/Practical     |  |
| No. of paddles | 01 No.         | OK     | Physical/Practical     |   |




**Instrument/ Component Name: Permanent Reaction Cuvette**

| Description | Specified  | Actual | Method of Verification | Verified by Signature   |
|-------------|------------|--------|------------------------|---|
| Quantity    | 45 Nos'    | OK     | Physical/Practical     |  |
| MOC         | Hard Glass | OK     | Physical/Practical     |   |
| Capacity    | 770 µL     | OK     | Physical/Practical     |   |

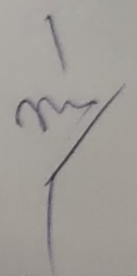
**Instrument/ Component Name: 7 Stage Laundry System**

| Description | Specified  | Actual | Method of Verification | Verified by Signature  |
|-------------|------------|--------|------------------------|--|
| Nozzles     | Nozzle - 1 | OK     | Physical/Practical     |  |
|             | Nozzle - 2 | OK     | Physical/Practical     |  |
|             | Nozzle - 3 | OK     | Physical/Practical     |  |
|             | Nozzle - 4 | OK     | Physical/Practical     |  |
|             | Nozzle - 5 | OK     | Physical/Practical     |  |
|             | Nozzle - 6 | OK     | Physical/Practical     |  |
|             | Nozzle - 7 | OK     | Physical/Practical     |  |

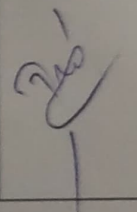


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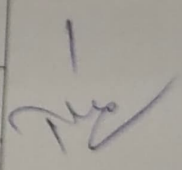
**Instrument/ Component Name: LightSource**

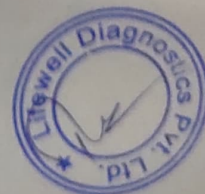
| Description | Specified | Actual | Method of Verification | Verified by Signature   |
|-------------|-----------|--------|------------------------|---|
| Watts       | 12 W      | OK     | Physical/Practical     |  |
| Volts       | 12 V      | OK     | Physical/Practical     |   |
| MOC         | Halogen   | OK     | Physical/Practical     |   |
| Quantity    | 01 No     | OK     | Physical/Practical     |   |

**Instrument/ Component Name: SampleCups**

| Description | Specified | Actual | Method of Verification | Verified by Signature  |
|-------------|-----------|--------|------------------------|--|
| Quantity    | 500 Nos'  | OK     | Physical/Practical     |  |
| MOC         | Plastic   | OK     | Physical/Practical     |  |
| Capacity    | 2 mL      | OK     | Physical/Practical     |  |

**Instrument/ Component Name: Software of EM 200**

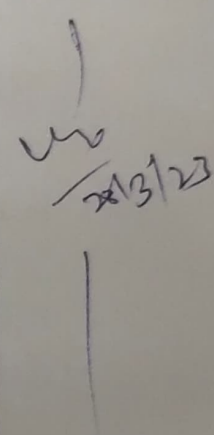
| Description | Specified      | Actual | Method of Verification | Verified by Signature   |
|-------------|----------------|--------|------------------------|---|
| Version     | 2018           | OK     | Physical/Practical     |  |
| CD number   |                | OK     | Physical/Practical     |   |
| Product     | EM- 200        | OK     | Physical/Practical     |   |
| Make        | Erba Transasia | OK     | Physical/Practical     |   |



**8.0 IDENTIFICATION AND VERIFICATION OF MATERIAL OF CONSTRUCTION**

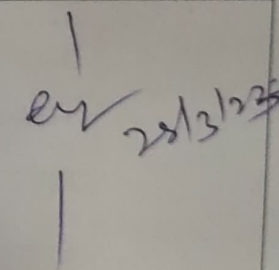
Identify and list down all components of the equipment for its material of construction.

*Method of Test may be Molybdenum Test, Test Certificate, Manual, etc.*

| Component (s)              | Material of Construction | Actual | Method of Verification | Verified by Sign & Date   |
|----------------------------|--------------------------|--------|------------------------|---|
| Sample Probe               | Teflon coated            | OK     | Physical/Practical     |  |
| Reagent Probe              | Teflon coated            | OK     | Physical/Practical     |   |
| Permanent Reaction Cuvette | Hard Glass               | OK     | Physical/Practical     |   |
| Light Source               | Halogen                  | OK     | Physical/Practical     |   |
| Reagent Bottle             | Plastic                  | OK     | Physical/Practical     |   |
| Sample Cups                | Plastic                  | OK     | Physical/Practical     |   |

**9.0 IDENTIFICATION AND VERIFICATION OF SUPPORTING UTILITIES**

List the supporting utilities and record whether or not they are properly connected and identified.

| Utilities       | Observation / Result | Verified by Sign & Date   |
|-----------------|----------------------|---|
| Power           | OK                   |  |
| Distilled Water | OK                   |   |
| Wash Solution   | OK                   |   |
| UPS             | OK                   |   |





|   |              |                      |                |
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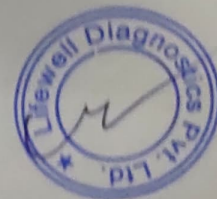



### 10.0 IDENTIFICATION OF STANDARD OPERATINGPROCEDURE

| SOP No.     | Title  |
|-------------|--|
| Operation   | Operation of Bio-Chemistry Random Analyzer   |
| Calibration | Calibration of Parameters  |
| Controls    | Checking of Controls for Parameters  |
| Maintenance | Maintenance / Checking of Distilled water, Waste, Wash solution, Cuvette rinse, Sample probe wash and Water save |
| Cleaning    | Cleaning of Instrument surface   |

### 11.0 ABBREVIATIONS

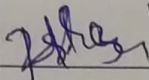
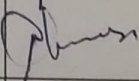
|            |                                     |
|------------|-------------------------------------|
| <b>SOP</b> | <b>Standard Operating Procedure</b> |
| <b>MOC</b> | Material of Construction            |
| <b>IQ</b>  | Installation Qualification          |



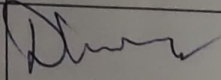
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| IQOQPQ HS Pathology Pvt.Ltd,Changarh |       |               |   |
| Instrument Name                      | EM200 | Instrument SN |   |

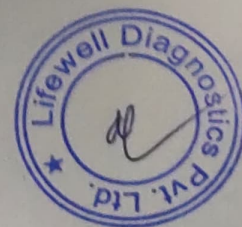
12.0 POSTAPPROVAL:

12.1 Checked by-

| Name          | Designation            | Signature  | Date    |
|---------------|------------------------|--|---------|
| Hari Shankar  | Service Engineer       |  | 28/3/23 |
| Dheeraj Gupta | Application Specialist |   | 28/3/23 |
|               |                        |  |         |

12.2 Customer Authorization:

| Name          | Designation | Signature  | Date    |
|---------------|-------------|--|---------|
| Mr.Dharmendra | Lab Manager |  | 28/3/23 |



|                                      |       |               |         |
|--------------------------------------|-------|---------------|---------|
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| IQOQPQ HS Pathology Pvt.Ltd,Changarh |       |               |         |
| Instrument Name                      | EM200 | Instrument SN | V200403 |

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## OPERATIONAL QUALIFICATION

As part of Operational qualification, the following checks shall be done and each test shall be recorded:

### **Instrument Start-up**

To check and establish the standard sequence to be followed, during start-up of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

### **Functional Checks**

To check and ensure that different functions (such as switching devices, indication / monitoring / recording devices, feedback system, etc.) for correct operation of the subjected instrument are working as expected.

### **Interlocks and Alarms Check**

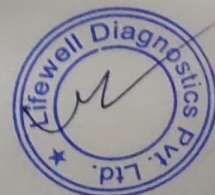
To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

### **Safety / Security Checks**

To check and ensure that the safety / security functions (such as program logging, process control, personnel safety systems, password check, etc.) to protect the instrument and personnel are working as expected.

### **Instrument Shut-down**

To check and establish the standard sequence to be followed, during shut-down of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

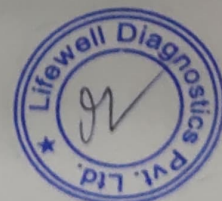


|                                      |       |               |                                 |
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| Instrument Name                      | EM200 | Instrument SN | V200403                         |

### 1.0 INSTRUMENT START-UP:

Refer the Operator's Manual for the procedures, for the following activities:

| Action   | Observation | Verified by  | Remarks |
|--|-------------|--------------|---------|
| Ensure that all the required electrical connections are properly connected.                                    | OK          | Hari Shankar | NA      |
| Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans. | OK          | Hari Shankar | NA      |
| Ensure the availability of XL Wash.  | OK          | Hari Shankar | NA      |
| Ensure the availability of Biohazard Waste.  | OK          | Hari Shankar | NA      |
| Ensure the availability of Normal Waste.   | OK          | Hari Shankar | NA      |
| Switch ON the rear switch of the analyzer.   | OK          | Hari Shankar | NA      |
| Switch ON the side switch of the analyzer.   | OK          | Hari Shankar | NA      |
| Switch ON the computer and start the analyzer application software.  | OK          | Hari Shankar | NA      |
| Initialization   | OK          | Hari Shankar | NA      |



|                 |       |               |         |
|-----------------|-------|---------------|---------|
| Instrument Name | EM200 | Instrument SN | V200403 |
|-----------------|-------|---------------|---------|

**2.0 FUNCTIONALCHECKS:****2.1 Maintenance:**

Refer the Operator's Manual for the procedures, for the following activities:

| Activity               | Observation | Verified by  | Remarks |
|------------------------|-------------|--------------|---------|
| Photometer functioning | OK          | Hari Shankar | NA      |
| Cuvette Rinse          | OK          | Hari Shankar | NA      |



|  |              |                      |   |
|--|--------------|----------------------|---|
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| <b>Instrument Name</b>                     | <b>EM200</b> | <b>Instrument SN</b> | <b>V200403</b>                                    |
|  |              |                      | <b>TRANSASIA<sup>®</sup></b><br>Bio-Medicals Ltd. |

### 2.2 Loading of Reagents:

Refer the Operator's Manual for the procedures, for the following activities:

| Action  | Observation | Verified by  | Remarks |
|---|-------------|--------------|---------|
| Reagent Level Scan,<br>Dead Volume Check &<br>2 Reagent Chemistry | OK          | Hari Shankar | OK      |

### 2.3 Calibration:

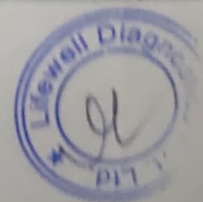
Refer the Operator's Manual for the procedures, for the following activities:

| Action                     | Observation | Verified by   | Remarks |
|----------------------------|-------------|---------------|---------|
| Blank (Distilled<br>Water) | OK          | Dheeraj Gupta | OK      |
| Standard (Multical)        | OK          | Dheeraj Gupta | OK      |

### 3.0 INTERLOCKS AND ALARMS CHECK:

Refer the Operator's Manual for the procedures, for the following activities:

| Action                                      | Observation | Verified by   | Remarks |
|---|-------------|---------------|---------|
| Less volume of<br>Distilled Water           | OK          | Dheeraj Gupta | OK      |
| Less volume of Wash<br>Solution             | OK          | Dheeraj Gupta | OK      |
| More volume of Bio-<br>Hazard waste         | OK          | Dheeraj Gupta | OK      |
| More volume of<br>Normal / General<br>waste | OK          | Dheeraj Gupta | OK      |



|   |              |                      |                |  |
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| <b>Instrument Name</b>                      | <b>EM200</b> | <b>Instrument SN</b> | <b>V200403</b> |  |

#### 4.0 SAFETY / SECURITY CHECKS:

Refer the Operator's Manual for the procedures, for the following activities:

| Action                             | Observation | Verified by   | Remarks |
|------------------------------------|-------------|---------------|---------|
| Password Check for Test Parameters | OK          | Dheeraj Gupta | OK      |
| Password Check for QC Mode         | OK          | Dheeraj Gupta | OK      |

#### 5.0 INSTRUMENT SHUT-DOWN:

Refer the Operator's Manual for the procedures, for the following activities:

| Action                                      | Observation | Verified by   | Remarks |
|---|-------------|---------------|---------|
| Sample Probe Wash                           | OK          | Dheeraj Gupta | OK      |
| Water Save                                  | OK          | Dheeraj Gupta | OK      |
| Switch OFF the computer.                    | OK          | Dheeraj Gupta | OK      |
| Switch OFF the side switch of the analyzer. | OK          | Dheeraj Gupta | OK      |
| Switch OFF the rear switch of the analyzer. | OK          | Dheeraj Gupta | OK      |



|                                      |       |               |         |   |
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| IQOQPQ HS Pathology Pvt.Ltd,Changarh |       |               |         |   |
| Instrument Name                      | EM200 | Instrument SN | V200403 |   |

**Protocol Performed By:**

| Name          | Designation            | Signature      | Date    |
|---------------|------------------------|----------------|---------|
| Hari Shankar  | Service Engineer       | <i>Hari</i>    | 28/3/23 |
| Dheeraj Gupta | Application Specialist | <i>Dheeraj</i> | 28/3/23 |

**Customer Authorization:**

| Name          | Designation | Signature         | Date    |
|---------------|-------------|-------------------|---------|
| Mr.Dharmendra | Lab Manager | <i>Dharmendra</i> | 28/3/23 |






## Performance Qualification

| S. No | Title                  |
|-------|------------------------|
| 1.0   | Pre approval           |
| 2.0   | Objective              |
| 3.0   | Scope                  |
| 4.0   | Pre- Requisites        |
| 5.0   | Test Plan              |
| 6.0   | Execution of Test Plan |
| 7.0   | Post Approval          |



|                                      |       |               |         |   |
|--------------------------------------|-------|---------------|---------|---|
| TRANSASIA BIOMEDICALS LIMITED        |       |               |         |  |
| IQOQPQ HS Pathology Pvt.Ltd,Changarh |       |               |         |   |
| Instrument Name                      | EM200 | Instrument SN | V200403 |   |

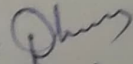
**1.0 PRE APPROVAL**

**I. Approval of the PO procedure**

Both HS Pathology, Varanasi and Transasia are jointly responsible for conducting the Performance Check of the Clinical Chemistry Analyzer, Model: ERBA – EM200, Serial No. v200403 in the clinical lab of HS Pathology as per the attached protocol.

**Protocol Performed By: Transasia Representative**

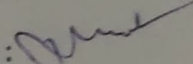
Name : Dheeraj Gupta  
 Title : PERFORMANCE-QUALIFICATION  
 Company : TRANSASIA BIO-MEDICALS LTD.

Signature: 

Date: 28/3/23

**Customer Authorizations:**

Name : Mr.Dharmendra  
 Title : PERFORMANCE-QUALIFICATION  
 Site : Changarh

Signature: 

Date: 28/3/23



|  |              |                      |   |
|--|--------------|----------------------|---|
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| <b>IQQPQ HS Pathology Pvt.Ltd,Changarh</b> |              |                      |   |
| <b>Instrument Name</b>                     | <b>EM200</b> | <b>Instrument SN</b> | <b>V200403</b>                                    |

## 2.0 OBJECTIVE

The objective of this protocol is to establish documented evidence for the Performance Qualification of EM 200 (Bio-Chemistry Random Analyzer) and to ensure that the results obtained are within the pre-determined Acceptance Criteria.

## 3.0 SCOPE


The Scope of this protocol is applicable to EM 200 (Bio-Chemistry Random Analyzer).

## 4.0 PRE-REQUISITES:

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification prior toPQ.
- Completion of Operational Qualification prior toPQ.



|                                      |       |               |   |
|--------------------------------------|-------|---------------|---|
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| Instrument Name                      | EM200 | Instrument SN |   |

**5.0 TEST PLAN**

The following tests shall be followed, during the Performance Qualification of EM200 (Bio-Chemistry Random Analyzer).

1. Glucose
2. Creanz
3. SGOT

- Data Analysis of PQ attached separately.


**Conclusion:-**

The study data has been determined, The system describes all Criteria outlined in its protocol  
The system is ready for specific uses

**6.0 ABBREVIATIONS**

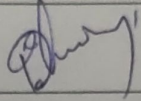
|     |                              |
|-----|------------------------------|
| SOP | Standard Operating Procedure |
| MOC | Material of Construction     |
| PQ  | Performance Qualification    |



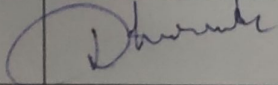
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|--------------------------------------|-------|-----------------------|---|
| TRANSASIA BIOMEDICALS LIMITED        |       |                       |  |
| IQOQPQ HS Pathology Pvt.Ltd,Changarh |       |                       |   |
| Instrument Name                      | EM200 | Instrument SN V200403 |   |

7.0 POSTAPPROVAL

7.1 Protocol done by-

| Name          | Designation            | Signature  | Date    |
|---------------|------------------------|--|---------|
| Dheeraj Gupta | Application Specialist |  | 28/3/23 |

7.2 Customer Authorization:

| Name          | Designation | Signature  | Date    |
|---------------|-------------|--|---------|
| Mr.Dharmendra | Lab Manager |  | 28/3/23 |

