**Quality System Procedure and forms were updated to align with IMDRF (International Medical Device Regulatory Forum) Annex Codes. Link to IMDRF Codes is here**

| No | Document Type |
|---|---|
| 1 | QSP 8.2.2 Complaint Handling |
| 2 | Form QSP 8.2.2-1 Complaint Handling |
| 3 | QSP 8.5 Corrective and Preventive Action |
| 4 | Form 8.5-1 Corrective and Preventive Action |
| 5 | QSP 8.3 Control of Nonconforming Product |
| 6 | Form QSP 8.3-1 Control of Nonconforming Product |

| Annex | Title | Description |
|---|---|---|
| A | Medical Device Problem | Types of device issues (e.g., interaction, manufacturing, chemical). |
| B | Type of Investigation | Categories of investigational approaches to determine root cause. |
| C | Investigation Findings | Specific outcomes or results uncovered during an investigation. |
| D | Investigation Conclusion | Summarized conclusions of investigative work. |
| E | Health Effects – Clinical Signs & Symptoms or Conditions | Observed clinical signs, symptoms, and conditions from adverse events. |
| F | Health Effects – Health Impact | Consequences/outcomes affecting the individual (e.g., severity, hospitalization). |
| G | Medical Device Component | Terminology for device parts/components involved in an adverse event. |

**The design control and IVD clinical performance study form was updated to calculate the cost associated with studies based on device, operators, instruments required and number of patient sample required etc**.

| | |
|---|---|
| 7 | QSP 7.3 Design and Development |
| 8 | Form Clinical Performance Studies Design |

# QSP Form

# Form 8.2-2-1 Complaint Form

**Revision History**

| Revision | Change Description | Initiator | Date |
|---|---|---|---|
| 1 | Initial Release | Vinod Rajendran | 09/18/2014 |
| 2 | Updated to comply with ISO 13485:2016 Standard | Karthik Krishna | 06/09/2017 |
| 3 | Updated Part C to address SGS 2021 minor audit finding CAR no.1 to verify that FMEA or 5 Whys are conducted, corrective actions are documented, and objective evidence is attached. | Karthik Krishna | 04/06/2021 |
| 4 | Updated Form to Comply to EU IVDR, FDA QSR and Rest of the World regulatory requirements | Violet Nunes | 06/18/2024 |
| 5 | Updated to align with IMDRF Regulations | Hemal Kurani | 07/09/2024 |

**Approval List**

| Department / Function | Print Name | Date | Signature Approvals |
|---|---|---|---|
| Quality Assurance Manager | | 06/18/2024 | |
| Management Representative | | 06/18/2024 | |

**PART A: Complaint Summary**

| | |
|---|---|
| COMP Number: | |
| Complaint Open Date: | |
| Complaint Close Date: | |
| Complaint Incident Date: | |
| Complaint Aware Date: | |
| Complaint Workflow Status: | |
| Complaint Type: | |
| Compliant Logger: | |
| **PART B: Customer Information** | |
| Customer Name: | |
| Customer Address: | |
| Customer Contact Name: | |
| Customer Phone Number: | |
| Customer Email Address: | |
| **PART C: Product Information** | |
| Product Type: | |
| Product Item Number: | |
| Product Name: | |
| Serial Number (Hardware): | |
| Lot Number (Reagent): | |
| Software Release Number: | |
| Product UDI Number: | |
| Sales Order Number: | |
| Source of Complaint: | |
| Medical Device? | |
| Item to be Returned: | |
| Returned Material Authorization Number: | |
| Customer to be Informed: | |
| Problem Code: | |

| | |
|---|---|
| (IMDRF Annex A) | |
| Type of Investigation:<br>(IMDRF Annex B) | |
| Investigation Findings:<br>(IMDRF Annex C) | |
| Product Component Describing the Parts which were involved in or affected<br>(IMDRF Annex G) | |
| Complaint Logger Summary: | |
| Complaint Logger Investigation Details: | |
| **Part D: Reportability Summary** | |
| Regulatory Analyst Assigned To: | |
| Regulatory Analyst Assignment Open Date: | |
| Regulatory Analyst Assignment Due Date: | |
| Risk Severity: | |
| Risk Occurrence: | |
| Risk Assessment Affected: | |
| Risk Assessment File: | |
| Field Corrective Action Required: | |
| Field Corrective Action Type | |
| Field Corrective Action Open Date: | |
| Field Corrective Action Due | |

| | |
|---|---|
| Date: | |
| Field Corrective Action Summary: | |
| Field Corrective Action Close Date: | |
| Reportable Security Incident | |
| Reportable Privacy Incident | |
| Adverse Event? | |
| Investigation Health Effects – Clinical Signs and Symptoms or Conditions Regulatory Assessment: (IMDRF Annex E) | |
| Investigation Health Impact Regulatory Assessment: (IMDRF Annex F) | |
| Health Impact Regulatory Assessment Summary: | |
| Reportable Adverse Event: | |
| Adverse Event Report Open Date: | |
| Adverse Event Report Due Date: | |
| Adverse Event Reported Countries: | |
| Adverse Event Report Summary: | |
| Adverse Event Report Close Date: | |
| Regulatory Impact to Registrations | |
| Regulatory Analyst Summary: | |
| Regulatory Analyst Assignment Close Date: | |
| **Part D: Investigation Details - Root Cause** | |

| | |
|---|---|
| Quality Analyst Assigned To: | |
| Quality Analyst Assignment Open Date: | |
| Quality Analyst Assignment Due Date: | |
| Investigation Required: | |
| No Investigation Required Justification: | |
| Investigation Root Cause Conclusion:<br>(IMDRF Annex D) | |
| Root Cause Details of the Problem as found in Investigation Conclusion:<br>(Hint – Use the FMEA, or 5 Whys as applicable shall be documented for IMDRF Annex D): | |
| Quality Analyst Investigation Root Cause Approval Date: | |
| **Part E: Investigation Details - Corrective Actions / Preventive Actions** | |
| Corrections Plan (Immediate Containment): | |
| Will the above plan fix the immediate problem? | |
| Corrections Plan Assigned To: | |
| Corrections Plan Open Date: | |
| Corrections Plan Due Date: | |
| Corrections Plan Completed Summary: | |
| Corrections Plan Close Date: | |
| Corrective Actions Plan: | |
| Corrective Actions Plan Assigned To: | |
| Corrective Actions Plan | |

| | |
|---|---|
| Assigned Open Date: | |
| Corrective Actions Plan Due Date: | |
| Corrective Actions Plan Completed Summary: | |
| Corrective Actions Plan Completion Close Date: | |
| Preventive Actions Plan: | |
| Preventive Actions Plan Assigned To: | |
| Preventive Actions Plan Assigned Open Date: | |
| Preventive Actions Plan Due Date: | |
| Preventive Actions Plan Completed Summary: | |
| Preventive Actions Plan Completion Close Date: | |
| Will the above plan fix the root cause of the problem so it will not recur / occur? | |
| Quality Analyst Investigation Corrective and Preventive Actions Approval Date: | |
| **PART F: Customer Resolution Details** | |
| Resolution Method: | |
| Resolution Summary: | |
| Resolution Provider Name: | |
| Resolution Close Date: | |
| **PART G: Extension Request** | |
| Extension Required: | |
| Reason for Extension: | |
| New Complaint Close Date: | |
| **PART H: Cross Reference** | |

| | |
|---|---|
| Ticket Number: | |
| Complaint Number: | |
| CAPA Number: | |
| NCR Number: | |
| SCAR Number: | |
| Software Defect Number: | |
| **PART I: Final QA Review, Approval and Complaint Closure** | |
| Quality Analyst Reviewed by: | |
| Quality Analyst Review Date: | |

| No | IVD Performance Studies Design Summary Rev 1 | Objective | Guidances | Statistical Method | Acceptance Criteria | Low End Sample Size | High End Sample Size | Low End (positive) Sample Size | Low End (negative) Sample Size | High End (positive) Sample Size | High End (negative) Sample Size | Sites | Reagent Lots | Operators | Number of Day | Runs per Day | Replicates per Run | Sample Levels | Sample Cost | Site Cost | Reagant Lot Cost | Operators Cost | Total Low-End Cost | Total High End Cost | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 3 | Analytical Performance - Reproducibility Study - 3 different sites and lots | The objective of the reproducibility study is to demonstrate the closeness of the agreement between the results of measurements of the same analyte carried out under changed conditions. This includes obtaining test results with the same method on identical test items in different labs, with different operators using different equipment. | CLSI EP05-A3, CLSI EP26-A | Imprecision CV = 100% x Standard Deviation (SD)/Mean | Lot-to-Lot Imprecision CV ± 20% CV, except ± 25% at LOD Site-to-Site Imprecision CV ± 20% CV, except ± 25% at LOD | 60 | 120 | 30 | 30 | 60 | 60 | 3 | 3 | 3 | 20 | 2 | 2 | High and Low Levels | 100 | 1000 | 1000 | 100 | 24600 | 36600 | f(x) = Q*(100G + 1000M +1000N +100O) | f(x) = Q*(100H + 1000M +1000N + 100O) |
| 4 | Analytical Performance - Precision/Reproducibility - Intra Assay | The objective of the Intra Assay Precision Study is to describe the variation of results within a data set obtained from one experiment. "Intra" refers to variation between replicates within a single assay run. Intra assay CV is used to monitor this variation within the same assay. | CLSI EP05-A3 | Imprecision CV = 100% x Standard Deviation (SD)/Mean | Intra Run (Within Run) CV ± 20% CV, except ± 25% at LOD | 20 | 50 | 10 | 10 | 25 | 25 | 1 | 1 | 1 | 1 | 1 | 3 | 3 Levels | 100 | 1000 | 1000 | 100 | 4100 | 7100 | | |
| 5 | Analytical Performance - Precision/Reproducibility - Inter Assay | The objective of the Inter Assay Precision Study is to demonstrate variation of results across repeated experiments. "Inter" refers to variation between separate runs of the same sample set, usually on different days. Inter assay CV monitors this precision. | CLSI EP05-A3 | Imprecision CV = 100% x Standard Deviation (SD)/Mean | Inter Assay CV ± 20% CV, except ± 25% at LOD | 30 | 60 | 15 | 15 | 30 | 30 | 1 | 1 | 1 | 3 | 1 | 2 | 3 Levels | 100 | 1000 | 1000 | 100 | 5100 | 8100 | | |
| 6 | Analytical Performance - Precision/Reproducibility - Inter Assay, Inter Lot | The objective of the Inter Assay Inter Lot Precision Study is to demonstrate variation between runs using different reagent lots. It monitors precision using inter assay CV across different assay days. | CLSI EP05-A3, EP09-A | Imprecision CV = 100% x Standard Deviation (SD)/Mean | Lot-to-Lot CV ± 20% CV, except ± 25% at LOD | 40 | 80 | 20 | 20 | 40 | 40 | 1 | 2 | 2 | 5 | 1 | 2 | 3 Levels | 100 | 1000 | 1000 | 100 | 7200 | 11200 | | |
| 7 | Analytical Performance - Linearity/Assay Reportable Range | No claims made on linearity. Linearity can be evaluated per CLSI EP06-Ed2 by preparing required dilution levels across the analytical measuring interval (AMI). | CLSI EP06-A | N/A | N/A | 10 | 40 | - | - | - | - | 1 | 1 | 1 | 1 | 1 | 3 | Full range | 100 | 1000 | 1000 | 100 | 3100 | 6100 | | |
| 8 | Analytical Performance - Traceability | Analytical traceability links results to a standard reference to ensure comparability and repeatability. It ensures results remain accurate across labs and systems. Traceability is validated through IQC programs that check for clinically tolerable measurement errors and detect deviations. | CLSI EP33-A | N/A | N/A | 30 | 50 | 15 | 15 | 25 | 25 | 1 | 1 | 1 | 1 | 1 | 3 | Standard levels | 100 | 1000 | 1000 | 100 | 5100 | 7100 | | |
| 9 | Analytical Performance - Expected Value | In IVD testing, the analytical expected value represents the measurement outcome expected when an IVD assay is tested under specific conditions with known control samples. This helps ensure diagnostic test accuracy and reliability by benchmarking against reference standards. | CLSI EP28-A3C | N/A | N/A | 50 | 100 | 25 | 25 | 50 | 50 | 1 | 1 | 1 | 1 | 1 | 1 | Expected levels | 100 | 1000 | 1000 | 100 | 7100 | 12100 | | |
| 10 | Analytical Performance - Limit of Blank | The objective of the Limit of Blank (LoB) Study is to determine the highest blank value expected in a sample containing no analyte, typically using water as a sample. | CLSI EP17-A2 | LoB = meanblank + Cp*(SDblank) | - | 30 | 50 | - | - | - | - | 1 | 1 | 1 | 3 | 1 | 1 | Blank level | 100 | 1000 | 1000 | 100 | 5100 | 7100 | | |
| 11 | Analytical Performance - Assay Cut Off | The Assay Cut Off Study aims to establish a decision point to distinguish between positive and negative results based on analyte-specific clinical significance. | CLSI EP12-A | Calculated during design validation using ROC curve analysis | - | 50 | 100 | 25 | 25 | 50 | 50 | 1 | 1 | 1 | 3 | 1 | 1 | Cut-off level | 100 | 1000 | 1000 | 100 | 7100 | 12100 | | |
| 12 | Analytical Performance - Limit of Detection | This study aims to establish the lowest amount of analyte that can be detected but not necessarily quantified as an exact value. | CLSI EP17-A2 | LoD = LoB + Cp*(SD low concentration sample) | - | 40 | 80 | 20 | 20 | 40 | 40 | 1 | 1 | 1 | 3 | 1 | 2 | LOD levels | 100 | 1000 | 1000 | 100 | 6100 | 10100 | | |
| 13 | Analytical Performance - Method Comparison Study - Analytical Accuracy | This study evaluates analytical accuracy by comparing results with a reference device (INOVA). The closeness of agreement with true analyte values will be assessed through positive predictive value, negative predictive value, and total agreement. | CLSI EP09-A3 | PPA > 90% NPA > 90% Total Agreement > 90% | - | 50 | 100 | 25 | 25 | 50 | 50 | 3 | 1 | 1 | 1 | 1 | 1 | Full range | 100 | 1000 | 1000 | 100 | 9100 | 14100 | | |
| 14 | Method Comparison Study - Matrix Comparison | A Matrix Comparison assesses how well an IVD test performs across different sample matrices (e.g., whole blood, plasma, serum, urine) to ensure consistent results across biological sample types. | CLSI EP14-A | N/A | N/A | 40 | 80 | 20 | 20 | 40 | 40 | 1 | 1 | 1 | 1 | 1 | 1 | All matrices | 100 | 1000 | 1000 | 100 | 6100 | 10100 | | |
| 15 | Clinical Study - Clinical Sensitivity, Clinical Specificity, Confidence Interval | Clinical Study - Clinical Sensitivity, Clinical Specificity, Confidence Interval | Clinical Study - Clinical Sensitivity, Clinical Specificity, Confidence Interval | Clinical Sensitivity = 100% x TP/(TP+FN) Clinical Specificity = 100% x TN/(FP +TN) Clopper-Pearson formula for calculating confidence interval | Literature comparison Report with 95% CI | 200 | 400 | 100 | 100 | 200 | 200 | 5 | 1 | 3 | 1 | 1 | 1 | Positive/Negative | 100 | 1000 | 1000 | 100 | 26300 | 46300 | | |
| 16 | Clinical Study - Clinical Cut Off | Defines the clinical cut-off using population data to provide decision points for diagnosing based on clinical significance. | CLSI EP12-A | N/A | N/A | 50 | 100 | 25 | 25 | 50 | 50 | 2 | 1 | 3 | 1 | 1 | 1 | Population levels | 100 | 1000 | 1000 | 100 | 8300 | 13300 | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 17 | Analytical Performance - Analytical Specificity - Interference | This study identifies causes of clinically significant bias due to specific interfering substances (e.g., hemoglobin, bilirubin, triglycerides) that may impact analyte measurement. | CLSI EP07 | Spiked sample % deviation ± 20% at each level tested | - | 30 | 60 | 15 | 15 | 30 | 30 | 1 | 1 | 1 | 1 | 1 | 1 | All interferences | 100 | 1000 | 1000 | 100 | 5100 | 8100 | | |
| 18 | Analytical Performance - Accelerated Stability - Shelf Life Stability | Verifies stability under accelerated conditions to support expiration dating. Stability is assessed from manufacture to the final day of usability under recommended conditions. | CLSI EP25-A | Deviation % = 100% x (Obtained - Expected)/(Expected) Arrhenius Equation with Accelerated Stability Testing data to predict shelf life. | Deviation % ± 25% for raw data and ± 20% for unit data at each time point Accelerated Study Shelf | 30 | 50 | - | - | - | - | 1 | 1 | 1 | 3 | 1 | 1 | Stability points | 100 | 1000 | 1000 | 100 | 5100 | 7100 | | |
| 19 | Analytical Performance - Real Time Stability - Shelf Life Stability | Real-time stability assessment to establish expiration dating, supporting stability claims throughout the product's lifespan in recommended storage conditions. | CLSI EP25-A | Deviation % = 100% x (Obtained - Expected)/(Expected) | Deviation % ± 25% for raw data and ± 20% for unit data at each time point Real Time Study Shelf Life | 30 | 50 | - | - | - | - | 1 | 1 | 1 | Real-time | 1 | 1 | Stability points | 100 | 1000 | 1000 | 100 | 5100 | 7100 | | |
| 20 | Analytical Performance - Stability - Open Kit Stability | Evaluates the stability of reagents after the kit has been opened but before active use, under recommended storage conditions. It assesses parameters such as potency, clarity, pH, and color stability. | CLSI EP25-A | Deviation % = 100% x (Obtained - Expected)/(Expected) | Deviation % ± 25% for raw data and ± 20% for unit data at each time point | 20 | 40 | - | - | - | - | 1 | 1 | 1 | 1 | 1 | 1 | Stability points | 100 | 1000 | 1000 | 100 | 4100 | 6100 | | |
| 21 | Analytical Performance - Stability - In Use Kit Stability | Tests stability during actual usage, accounting for practical handling conditions such as repeated opening, exposure, and potential contamination. | CLSI EP25-A | Deviation % = 100% x (Obtained - Expected)/(Expected) | Deviation % ± 25% for raw data and ± 20% for unit data at each time point | 20 | 40 | - | - | - | - | 1 | 1 | 1 | 1 | 1 | 1 | Stability points | 100 | 1000 | 1000 | 100 | 4100 | 6100 | | |
| 22 | Shipping Study | Confirms stability of the shipping container and its contents under simulated transport and temperature conditions. | CLSI EP25-A | N/A | N/A | 20 | 40 | - | - | - | - | 1 | 1 | 1 | 1 | 1 | 1 | Stability points | 100 | 1000 | 1000 | 100 | 4100 | 6100 | | |
| 23 | Specimen Stability Study | Confirms stability across various specimen types under specific collection and processing protocols for reliable diagnostic results. | CLSI EP25-A | N/A | N/A | 30 | 50 | - | - | - | - | 1 | 1 | 1 | Varies | 1 | 1 | Storage levels | 100 | 1000 | 1000 | 100 | 5100 | 7100 | | |
| | **Training Sample Set - Accuracy and Precision** | The objective of the training is to facilitate learning and development of the complete assay by the Clinical Laboratory Specialist and Clinical Laboratory Assistants test personnels. This will include<br><br>1) Assay Workflow<br>2) Assay Processing SOP, Protocol and Steps<br>3) Sample Preparation<br>4) Assay Kit<br>5) Equipment Calibration and Preventative Maintenance<br>6) Quality Control<br>7) Safety<br>8) Sample Data Handling<br><br>The study site personnel will be trained by the sponsor personnel who will be running the representative set of positive and negative samples. | CLSI EP09-A2, CLSI EP05-A3 | PPA = 100% x a/(a+c)<br>NPA = 100% x d/(b+d)<br>Total Agreement = 100% x (a+d)/(a+b+c+d)<br>Imprecision CV = 100% x Standard Deviation (SD)/Mean | PPA > 95%<br>NPA > 95%<br>Total Agreement > 95%<br>Imprecision CV ± 20% CV, except ± 25% at LOD | 6 | 12 | 3 | 3 | 6 | 6 | 1 | 1 | 3 | 1 | 2 | 1 | High and Low Levels | 100 | 1000 | 1000 | 100 | 5800 | 7000 | | |
| | Familiarization Sample Set - Accuracy and Precision<br>(Familiarization period) | The objective of the device familiarization is to ensure that study site by the Clinical Laboratory Specialist and Clinical Laboratory Assistants by test personnels can independently run the test and demonstrate complete proficiency. This will include:<br><br>1) Operation of Instruments<br>2) Handling of Assay Kits<br>3) Operators to become familiar with the evaluaton SOP and assay protocol<br>4) Independent Execution of Assay Tests<br>5) Test Run Batch Records Documentation<br>6) Test Data Handling and Storage<br><br>The study site personnel will independently test the respresentative set of positive and negative samples. | CLSI EP09-A2, CLSI EP05-A3 | PPA = 100% x a/(a+c)<br>NPA = 100% x d/(b+d)<br>Total Agreement = 100% x (a+d)/(a+b+c+d)<br>Imprecision CV = 100% x Standard Deviation (SD)/Mean | PPA > 95%<br>NPA > 95%<br>Total Agreement > 95%<br>Imprecision CV ± 20% CV, except ± 25% at LOD | 12 | 24 | 6 | 6 | 12 | 12 | 2 | 2 | 6 | 2 | 4 | 2 | High and Low Levels | 100 | 1000 | 1000 | 100 | 23200 | 28000 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |