**Validation Summary Report for Quantitative Method**

|  |  |  |
| --- | --- | --- |
| (Please fill in the table with your laboratory’s information  and details on the method being validated) | | |
| **Date(s) Validation Performed:** |  | |
| **Laboratory Name:** |  | |
| **City, Country:** |  | |
| **Instrument/Method/Reagent being validated:** |  | |
|  | Primary  Back-up | |
| (if applicable)  **Serial Number(s):** |  | |
| **Analyte(s):** |  | |
| **Kit Name:** |  | |
| **Sample Type(s):** |  | |
| **Reason for Validation:** | Initial Validation | Re-validation (choose one below)  ☐ Instrument move  ☐ Instrument modified  ☐ Method change  ☐ Other: ­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Regulatory Status:**  (check all that apply) | FDA Approved  FDA Cleared  CE Marked  EUA  None | |

**Procedure:** Refer to the (insert lab name) Validation Plan for (insert instrument name and serial number). This summary was written using “VAL 2001\_Quantitative Validation Guidelines” as a reference, please refer to this document if more details are needed.

**Results:** All raw data reports and statistical analysis can be found in the (insert location details).

1. **Precision****-** Identify the materials used for short-term and long-term testing
   1. Short-Term

(Insert number of samples and materials) were used on the same run.

**OR-**

(Insert number of samples and materials) were used within the same day.

* (E.g. 20 high- and low-quality control samples were used on the same run.)

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| --- | --- | --- | --- | --- | --- |
| Analyte | Expected Results | | Observed Results: Short-term | | Acceptability |
| Manufacturer’s Precision | 25% of CLIA | Normal Control | Abn Control |
| CV% | CV% |
| (ALT) | (2.60%) | (5%) | (2.60%) | (4.30%) | (Acceptable) |
| (WBC) | (2.60%) | (3.75%) | (2.60%) | (3.30%) | (Acceptable) |
| (PT) | (3.50%) | (3.75%) | (2.60%) | (4.30%) | (Acceptable) |

* 1. Long-Term

(insert sample material) were run two times per day for 10 days.

**OR-**

(insert sample material) were run once per day for 20 days.

**OR-**

(insert sample material) were run 5 times per day for 4 days.

* (E.g. High- and low-quality controls were run two times per day for 10 days.)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Analyte | Expected Results | | Observed Results: Long-term | | Acceptability |
| Manufacturer’s Precision | 33% of CLIA | Normal Control | Abn. Control |
| CV% | CV% |
| (ALT) | (3.30%) | (6.60%) | (3.80%) | (4.30%) | (Acceptable) |
| (WBC) | (3.30%) | (4.95%) | (3.80%) | (4.30%) | (Acceptable) |
| (PT) | (4.50%) | (4.95%) | (3.80%) | (4.30%) | (Acceptable) |

1. **Accuracy-** Identify the reference method and materials used to establish accuracy.
   1. (Insert number of samples and materials) were used to correlate with (insert laboratory name) in (location) on the (test method)

* E.g. 20 patient samples were used to correlate with XYZ Laboratory in Baltimore, Maryland on the Cobas Integra (SN # 1234).

**OR-**

Accuracy was established by using (insert number of samples, proficiency provider, year and panel name) with results compared to the peer means.

* E.g. Accuracy was established by using 15 CAP samples from the 2022 FH9 survey with results compared to the peer means and 5 patient samples or 5 CAP samples from the 2023 FH9 A event

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte | Total Allowable Error | Correlation Coefficient (R) | Linear Regression Statistics | | Error Index Range | % of Error Indices  -1.0 to 1.0 | Acceptability |
| Expected  >0.975 | Slope | Intercept | Expected  -1.0 to1.0 | Expected  ≥ 95% |
| (ALT) | (0.5U/L or 20%) | (0.997) | (1.002) | (2.19) | (-0.29-1.05) | (95%) | (Acceptable) |
| (WBC) | (0.12 or 15%) | (0.997) | (1.002) | (2.19) | (-0.29-1.05) | (95%) | (Acceptable) |
| (PT) | (15%) | (0.997) | (1.002) | (2.19) | (-0.29-1.05) | (95%) | (Acceptable) |

* 1. **Alternate Comparison-** Required only for analytes identified as unacceptable in section 2. a.

Alternate Correlation was performed with (Insert name) Laboratory in (location) on the (test method)

* E.g. Alternate Correlation was performed with XYZ Laboratory in Baltimore, Maryland on the Cobas Integra (SN#1234).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Analyte | Total Allowable Error | Correlation Coefficient (R) | MDP Error Index Range | | Acceptability |
| Expected  >0.975 | Expected  -1.0 to1.0 | 100% of Error Indices:  -1.0 to 1.0 |
| (ALT) | (0.5U/L or 20%) | (0.997) | (-0.29-1.00) | (yes) | (Acceptable) |
| (WBC) | (0.12 or 15%) | (0.997) | (-0.29-1.00) | (yes) | (Acceptable) |
| (PT) | (15%) | (0.997) | (-0.29-1.00) | (yes) | (Acceptable) |

1. **Linearity –** Identify the method or materials used to establish linearity.

*Note for Coagulation: Linearity study is not applicable, skip to next section.*

Linearity was established from (insert number of samples) run in duplicate from the (insert provider, year and panel name)

* E.g. Linearity was established from 6 samples run in duplicate from the CAP 2022 LN2-B panel.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Analyte | Linear Regression Statistics | | Allowable Systematic Error | Linear Range Verified | Evaluation |
| Slope | Intercept | 50% of TEa |
| (ALT) | (0.97) | (0.282) | (10%) | (20-350) | (Linear) |
| (WBC) | (0.97) | (0.282) | (7.50%) | (1.0-25) | (Linear) |

1. **Analytical Measurement Range (AMR) and Clinical Reportable Range (CRR)-**

*Note for Coagulation AMR and CRR studies are not applicable, skip to next section.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte | Mfg’s AMR | Low Value Verified | High Value Verified | Reportable Range | Dilutions | CRR | DAIDS Toxicity Grade 4 |
| (ALT) | (5-700 U/L) | (2.5) | (770) | (5-700) | (1:10) | (5-7000) | (>381) |
| (WBC) | (0.5-25 109/uL) | (1.0) | (25) | (1.0-25) | (1:10) | (1.0-250) | (<1.0) |

1. **Analytical Sensitivity and Specificity-** See below for examples of how to enter information from the package insert into the summary form.

**Chemistry**

|  |  |  |
| --- | --- | --- |
| **Summary of Manufacturer’s Claims for Sensitivity and Specificity** | | |
| **Analyte** | **Specificity (Interfering Substances)** | **Sensitivity** |
| ALT | Icterus – No significant effect  Hemolysis – No significant effect  Lipemia – No significant effect; >Abs flagging may occur  Other –Calcium dobesilate may cause low results | 5 U/L |
| AST | Icterus – No significant effect  Hemolysis – No significant effect  Lipemia – No significant effect; >Abs flagging may occur | 5 U/L |
| Albumin | Icterus –No significant effect  Hemolysis- No significant effect  Lipemia- No significant effect | 0.2 g/dL |

**Hematology**

|  |  |  |
| --- | --- | --- |
| **Summary of Manufacturer’s Claims for Sensitivity and Specificity** | | |
| **Analyte** | **Specificity (Interfering Substances)** | **Sensitivity** |
| WBC: | **Unlysed Red Cells** - False increase  **Multiple Myeloma** - False increase  **Leukemia** - False decrease  **Chemotherapy** - False decrease  **Cryoglobulins** - False increase  **WBC Agglutination** - False decrease  **PLT Agglutination** - False increase | 0 K/uL |
| RBC: | **Agglutinated RBC’s** - False decrease & falsely elevated MCH, MCHC & MCV  **Cold Agglutinins** - False decrease & falsely elevated MCV | 0 1012/L |
| HGB | **High WBC** - An extremely high WBC will cause excessive light scatter. In these cases use reference methods.  **Lipemia** - Significant interference - Use a reference method and plasma blank.  **Turbidity** - False increase, abnormal MCH, MCHC values & an increased baseline on the leading edge of the WBC histogram.  **Fetal Blood** - False increase. | 0 g/dL |
| HCT | **RBC agglutination** - Inaccurate results. | 0 g/dL |
| MCV | **RBC agglutination** - Inaccurate results.  **Large Platelets (excessive numbers)** - Inaccurate results  **High WBC’s** - Inaccurate results | N/A |
| MCH | Calculated based on HGB & RBC -refer to those for MCH limitations. | N/A |
| MCHC | Calculated based on HBG & HCT - refer to those for MCHC limitations. | N/A |
| RDW | Calculated based on RBC - refer to RBC count for limitations | N/A |
| PLTs | **Microcytes, Schistocytes & WBC Fragments** - False increase  **RBC Agglutination** - Falsely decrease  **Giant Platelets (large number)** - False decrease  **Chemotherapy** - False decrease  **Hemolysis** - False increase  **ACD Blood** - False decrease  **Increased Triglycerides and/or Cholesterol** - Inaccurate results  **Platelet Agglutination** - False decrease | 0 K/uL |
| MPV | **Giant Platelets** - Inaccurate results  **Microcytes, Schistocytes & WBC Fragments** - Inaccurate results  **RBC Agglutination** - Inaccurate results  **Chemotherapy** - Inaccurate results | N/A |
| LYM % & Absolute | **Erythroblasts** - False increase  **Parasites** - False increase  **Unlysed RBC’s** - False increase  **WBC limitations** - Pertains to differential enumeration also | 0 K/uL |
| MON % & Absolute | **Large lymphocytes** - False increase  **Atypical Lymphocytes** - False increase  **Blasts** - False increase  **Basophils (excessive numbers)** - False increase  **WBC limitations** - Pertains to differential enumeration also | 0 K/uL |
| NEU % & Absolute | **Eosinophils (excessive numbers)** - Inaccurate results  **Immature granulocytes** - Inaccurate results  **Plasma cells** - Inaccurate results  **WBC limitations** - Pertains to differential enumeration also | 0 K/uL |
| EOS % Absolute | **Abnormal granules** - Inaccurate results  **WBC limitations** - Pertains to differential enumeration also | 0 K/uL |
| BAS % & Absolute | **WBC limitations** - Pertains to differential enumeration also | 0 K/uL |

**Coagulation**

|  |  |  |
| --- | --- | --- |
| **Summary of Manufacturer’s Claims for Sensitivity and Specificity** | | |
| **Analyte** | **Specificity (Interfering Substances)** | **Sensitivity** |
| Pt | Hemolysis- Can cause decrease times.  Lipemia- Can cause increase times  Icterus- No significant effect. |  |
| APtt | Hemolysis- Can cause decrease times.  Lipemia- Can cause increase times  Icterus- No significant effect. |  |
| Fibrinogen | Hemolysis- No significant effect.  Lipemia- Can cause increase times  Icterus- No significant effect. |  |

1. **Reference ranges-** Describe the methods used to establish or verify reference ranges for each analyte.
2. Reference range was transfered/adopted from (insert the source/published range) or established.
3. Include information on how “normal” subjects were screened, the total number of subjects included, and any other pertinent information.
4. See below for examples of how to enter information for reference ranges into the summary form.

**Chemistry**

|  |  |  |  |
| --- | --- | --- | --- |
| **Analyte** | **Adult Reference Ranges** | **Reference Range Cited** | **% Verified**  **(Expected ≥90%)** |
| Albumin | 3.4-5.0 mg/dL | Dimension Manufacturer’s range | 100% |
| Alk Phos | 38-126 U/L | Caribbean Reference ranges | 95% |
| ALT | 9-72 U/L | Caribbean Reference ranges | 95% |
| Amylase | 25-125 U/L | Panamanian Reference ranges | 95% |
| AST | 0-37 U/L | Panamanian Reference ranges | 100% |
| BUN | 7-18 mg/dL | Dimension Manufacturer’s range | 100% |
| Cholesterol | 0-200 mg/dL | N/A\* | N/A\* |
| Creatinine | 0.5-1.4 mg/dL | Panamanian Reference ranges | 95% |
| D. Bilirubin | 0.0-0.3 mg/dL | Dimension Manufacturer’s range | 100% |
| Glucose | 70-110 mg/dL | Dimension Manufacturer’s range | 100% |
| HDL Cholesterol | 40-60 mg/dL | N/A\* | N/A\* |
| LDL Cholesterol | <130.00 mg/dL | N/A\* | N/A\* |
| LDH | 100-190 U/L | Dimension Manufacturer’s range | 95% |
| Lipase | 20-300 U/L | Caribbean Reference range | 90% |
| T. Bilirubin | 0.1-1.2 mg/dL | Caribbean Reference range | 95% |
| Total Protein | 6.4-8.2 g/dL | Dimension Manufacturer’s range | 100% |
| Triglycerides | 0-150 mg/dL | N/A\* | N/A\* |
| Uric Acid | 2.6-7.2 mg/dL | Dimension Manufacturer’s range | 100% |

**Hematology**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Analyte** | **Reference Population** | **Adult Male** | **% Verified**  **(Expected >90%)** | **Adult Female** | **% Verified**  **(Expected >90%)** | **Acceptability** |
| WBC (K/uL) | Ugandan | 3.2 - 8.2 | 90% | 3.6 - 10.3 | 100% | Acceptable |
| Neutrophil % | Ugandan | 21.6 - 66.9 | 100% | 29.3 - 64.0 | 90% | Acceptable |
| Lymphocyte % | Coulter Inst. range | 21.2 - 59.8 | 95% | 26.5 - 59.2 | 90% | Acceptable |
| Monocytes % | Coulter Inst. range | 4.3 - 9.6 | 95% | 3.5 - 10.9 | 95% | Acceptable |
| Eosinophils % | Coulter Inst. range | 1.1 - 28.8 | 95% | 1.0 - 10.9 | 95% | Acceptable |
| Basophils % | Coulter Inst. range | 0.3 - 2.0 | 100% | 0.3 - 1.0 | 100% | Acceptable |
| Neutrophil Abs. | Coulter Inst. range | 1.11 - 3.78 | 95% | 1.21 - 6.01 | 95% | Acceptable |
| Lymphocyte Abs. | Coulter Inst. range | 1.04 - 3.42 | 90% | 1.33 - 3.66 | 100% | Acceptable |
| Monocytes Abs. | Coulter Inst. range | 0.20 - 0.61 | 95% | 0.20 - 0.76 | 95% | Acceptable |
| Eosinophils Abs. | Coulter Inst. range | 0.05 - 1.47 | 95% | 0.05 - 0.73 | 100% | Acceptable |
| Basophils Abs. | Coulter Inst. range | 0.01 - 0.14 | 100% | 0.01 - 0.08 | 95% | Acceptable |
| RBC 1012/L | Tanzanian | 3.64 - 5.93 | 90% | 3.22 - 5.01 | 90% | Acceptable |
| Hemoglobin (g/dL) | Tanzanian | 11.5 - 15.8 | 90% | 9.6 - 14.9 | 95% | Acceptable |
| Hematocrit % | Tanzanian | 33.1 - 45.9 | 95% | 27.4 - 42.7 | 95% | Acceptable |
| MCV (fL) | Coulter Inst. range | 70 - 94 | 95% | 73 - 94 | 95% | Acceptable |
| MCH (pg) | Coulter Inst. range | 23.3 - 33.1 | 95% | 24.5 - 32.9 | 90% | Acceptable |
| MCHC (g/dL) | Coulter Inst. range | 33.1 - 35.6 | 95% | 33.1 - 35.6 | 90% | Acceptable |
| RDW % | Coulter Inst. range | 10.8 - 15.9 | 90% | 11.2 - 17.2 | 100% | Acceptable |
| Platelets (K/uL) | Ugandan | 61 - 345 | 95% | 103 - 383 | 95% | Acceptable |
| MPV (fL) | Coulter Inst. range | 7.2 - 10.2 | 95% | 7.2 - 10.3 | 100% | Acceptable |

**Coagulation**

**Adult:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Analyte** | **Adult Reference Ranges** | | **% Verified**  **(Expected >90%)** |
| **Pt** | | 11.0-14.0 seconds | 100% |
| **Aptt** | | 27-40 seconds | 100% |
| **Fibronogen** | | 156-400 mg/dl | 100% |

**Pediatric:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Analyte** | **Age** | **Normal Range** | **% Verified**  **(Expected >90%)** |
| **Pt(sec)** | Preterm Infant (30-36 week) | 14.6-16.9 | \*\*\* |
|  | Newborn-term | 10.1-15.9 | \*\*\* |
|  | 1-5 year | 10.6-11.4 | \*\*\* |
|  | 6-10 year | 10.1-12.1 | \*\*\* |
|  | 11-16 year | 10.2-12.0 | \*\*\* |
|  |  |  |  |
| **aPtt(sec)** | Preterm Infant (30-36 week) | 80-168 | \*\*\* |
|  | Newborn-term | 31.3-54.3 | \*\*\* |
|  | 1-5 year | 24-36 | \*\*\* |
|  | 6-10 year | 26-36 | \*\*\* |
|  | 11-16 year | 26-37 | \*\*\* |
|  |  |  |  |
| **Fibrinogen (mg/dl)** | Preterm Infant (30-36 week) | 150-373 | \*\*\* |
|  | Newborn-term | 167-309 | \*\*\* |
|  | 1-5 year | 170-405 | \*\*\* |
|  | 6-10 year | 157-400 | \*\*\* |
|  | 11-16 year | 154-448 | \*\*\* |

**\*\*\***Ranges to be verified over time as appropriate data becomes available.

**Reference Range Approval**

Approved

Not Approved

|  |  |
| --- | --- |
| **Medical Director:** |  |
| **Date:** |  |

|  |  |
| --- | --- |
| **Prepared by:** |  |
| **Date:** |  |

**Method Approval**

Approved

Not Approved (provide recommendations/corrective actions below)

Additional comments, if needed:

|  |  |
| --- | --- |
| **Laboratory Director:** |  |
| **Date:** |  |