

Method Validation Worksheets

Refer to QA Manual for instructions on using the Method Validation Worksheets. Also, visit the Qualigen, Inc. website at www.qualigeninc.com for “On Q” Training.

1. Verify Accuracy and Precision – this is performed once per analyzer per assay during installation and training.

2. Verify Reportable Ranges (Calibration Verification) – this is performed initially at start up and routinely every 6 months thereafter.

3. Identify your Reference Ranges

Free T4 - Verify Accuracy and Precision. Run C1 and C2 five times each upon installation.

C1 (Low Control Range)

C2 (High Control Range)

1

Control C1

Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

Control C2

Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

2

Control C1

Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

Control C2

Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

3

Control C1

Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

Control C2

Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

4

Control C1

Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

Control C2

Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

5

Control C1

Write "C1", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

Control C2

Write "C2", the control kit lot number, and your initials on the FastPack® IP peel-off label and place it here.

Calculating Accuracy and Precision

From the Control Range Card, enter the Upper and Lower limits as well as the Mean of the control material's acceptable range into the appropriate sections below.

Free T4 - C1

Lower Limit

Mean

Upper Limit

Calculate the Average of all 5 values $(1+2+\dots+5)/5$:

AVG = _____

Calculate the Standard Deviation of all 5 values:

SD = _____

Calculate the Install Precision Specification:

IPS = _____

$$IPS = 0.8 \times SD \text{ Spec} \quad \left\{ \begin{array}{l} \text{If AVG} < 1, SD \text{ Spec} = 0.115 \\ \text{If AVG} \geq 1, SD \text{ Spec} = 0.115 \times \text{AVG} \end{array} \right\}$$

Calculate the Chi-Squared Statistic¹ (χ^2_{stat}):

$\chi^2_{\text{stat}} =$ _____

$$\chi^2_{\text{stat}} = SD^2 \times \left(\frac{2.5}{IPS^2} \right)$$

Free T4 - C2

Lower Limit

Mean

Upper Limit

Calculate the average of all 5 values $(1+2+\dots+5)/5$:

AVG = _____

Calculate the standard deviation (SD) of all 5 values:

SD = _____

Calculate the Install Precision Specification:

IPS = _____

$$IPS = 0.8 \times SD \text{ Spec} \quad \left\{ \begin{array}{l} \text{If AVG} < 1, SD \text{ Spec} = 0.115 \\ \text{If AVG} \geq 1, SD \text{ Spec} = 0.115 \times \text{AVG} \end{array} \right\}$$

Calculate the Chi-Squared Statistic (χ^2_{stat}):

$\chi^2_{\text{stat}} =$ _____

$$\chi^2_{\text{stat}} = SD^2 \times \left(\frac{2.5}{IPS^2} \right)$$

Chi-Squared Statistic (χ^2) statistical analysis is an accepted methodology for precision performance evaluations. Refer to CLSI (Clinical and Laboratory Standards Institute) EP5 approved guideline "Evaluation of Precision Performance of Quantitative Measurement Procedures".

Free T4 Accuracy and Precision

Analyzer SN:

Circle Your Response

| | | | | |
|----------|--------------------------------------------------------------------|---|---|-----|
| 1 | Do all control testing values fall within the acceptable QC range? | Y | N | N/A |
| 2 | Is the C1 control $\chi^2_{\text{stat}} < \chi^2_{\text{crit}}?$ | Y | N | N/A |
| 3 | Is the C2 control $\chi^2_{\text{stat}} < \chi^2_{\text{crit}}?$ | Y | N | N/A |

The critical value for the Chi-Squared Statistic (χ^2_{crit}) based on 5 measurements and a 95% confidence level is 7.81.

If you can provide a "Yes" answer in all 3 question categories above, check the box below to accept the manufacturer's claims for accuracy and precision. If the answer in any of the above question categories is No, check the box that you DO NOT accept the manufacturer's claims for accuracy and precision and contact Qualigen System Support.

- Accept the manufacturer's claims for accuracy and precision
- DO NOT accept the manufacturer's claims for accuracy and precision

Free T4

Verify Reportable Ranges (Calibration Verification) every 6 months

Verify that the FastPack® IP System is accurate to the limits of the reportable range specified by Qualigen, Inc. by using the FastPack® IP Free T4 Method Verification Kit.

| | |
|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p style="text-align: center;">Low</p> <p>Target <input data-bbox="311 443 539 499" type="text"/></p> | <p style="text-align: center;"><i>Write "Low Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here</i></p> |
| <p style="text-align: center;">Mid</p> <p>Range <input data-bbox="300 863 539 919" type="text"/></p> | <p style="text-align: center;"><i>Write "Mid Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here</i></p> |
| <p style="text-align: center;">High</p> <p>Target <input data-bbox="311 1283 539 1339" type="text"/></p> | <p style="text-align: center;"><i>Write "High Verifier", the lot number, and your initials on the peel-off FastPack® label and place it here</i></p> |

The Low Verifier result must be < 0.40 ng/dL and the High Verifier result must be > 6.0 ng/dL to accept the Manufacturer's Reportable Range. If either result is different than the above, record the reportable range based on actual observed values. The mid value must be within the range designated on the range card. If it is not, repeat the test. If any value is out of range after repeating the test, contact Qualigen System Support.

- Accept Manufacturer Reportable Range: 0.40 ng/dL to 6.0 ng/dL
- DO NOT Accept. Derived Reportable Range: _____

Identify the Reference Ranges for your Practice

Qualigen has obtained serum samples from 207 individuals (99 random males and 108 random females). Samples were obtained from normal, healthy blood donors without any clinically abnormal indications. Free T4 levels were determined using the FastPack® IP Free T4 Immunoassay in conjunction with the FastPack® IP System analyzer in order to establish the Free T4 concentration in the normal population. The expected normal range for the FastPack® IP Free T4 Immunoassay is 0.5 – 1.4 ng/dL which reflects the expected normal range for the donor population of this study group.

Determine the reference range appropriate for your patient population.

| Type of Patient | Your Reference (Normal) Ranges |
|-----------------|--------------------------------|
| Normal | |
| Others: | |
| | |
| | |

OK to begin testing

NOT OK to begin testing

Testing Analyst/Technical Consultant

Date

Laboratory Director

Date