TECHNICAL SPECIFICATIONS

# PreTRM® Test for Risk Management

## Intended Use / Indications for Use

The PreTRM Test for Risk Management predicts the risk of spontaneous preterm birth (before 37 weeks) in asymptomatic women (no signs or symptoms of preterm labor with intact membranes) ≥18 years old with a singleton pregnancy.[1,2] The PreTRM Test is performed via a single blood draw between 18wk - 20wk/6d (126-146 days) gestation.[3]

The PreTRM Test is a laboratory-developed test (LDT) and is performed exclusively by Sera Prognostics Clinical Laboratory, Salt Lake City, Utah.[3]

## Analytical Test Method

### SAMPLE WORKFLOW

Samples are enriched for the targeted proteins using affinity capture after having been reconstituted from the sample collection device using an extraction buffer. Enriched samples are then digested with a protease to generate peptides that serve as surrogate analytes for the proteins of interest. Samples are fortified with stable isotope internal standards (SIS).

The abundances of diagnostic and quality control proteins from fully processed samples are detected by liquid chromatography- mass spectrometry.

### DATA ANALYSIS

A proteomic risk score is calculated using the internal standard–normalized relative abundances of two signature analytes: insulin-like growth factor-binding protein 4 (IGFBP4) and sex hormone-binding globulin (SHBG). This score is integrated with maternal clinical and demographic variables, including parity, body mass index (BMI), age, history of type I or II diabetes, chronic hypertensive disorder, maternal history of preterm birth (delivery prior to 37 weeks gestation), and prior preeclampsia—all of which are recognized clinical risk factors for preterm birth. The PreTRM Test reports the individual qualitative risk of spontaneous preterm birth before 37 weeks gestation as either “higher risk” or “not higher risk,” based on a proprietary regression algorithm and a validated decision threshold.

## Process Controls

- Depletion Efficiency
- Digestion Performance
- Proteomic Score-Based Batch Quality Control
- Matrix Verification
- Abundance Measurement Within Validated Measurement Range

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# Performance Characteristics

## LINEARITY AND LIMITS OF QUANTITATION

The lower and upper limits of quantitation were determined from linearity experiments, in which recombinant IBP4 and SHBG proteins were spiked into blank serum matrix at eleven known nominal concentrations (Cal2 – Cal12). The upper limit of quantitation (ULOQ) was the highest nominal concentration of each analyte that yielded an acceptable correlation ($R^2$) and had a calculated concentration within 20% of the nominal concentration and had a CV ≤20%. The lower limit of quantitation (LLOQ) met the same criteria but also had a signal-to-background > 5. Data was obtained from LCMS instruments denoted in this document as Instrument 1 (INST 1) and Instrument 2 (INST 2).

**Table 1.** Linearity test accuracy results for SHBG

Values in green were deemed to meet all linearity acceptance criteria for SHBG.

**Linearity Test Calculated vs. Nominal Concentration Results for SHBG**

| Sample | Nominal Concentration (ug/mL) | Lowest Observed RR *LLOQ | Highest Observed RR **ULOQ | INST 1 Day1 (% bias) | INST 2 Day1 (% bias) | INST 1 Day2 (% bias) | INST 2 Day2 (% bias) | INST 1 Day3 (% bias) | INST 2 Day3 (% bias) |
|---|---|---|---|---|---|---|---|---|---|
| Cal2 | 1.38 | 0.08* | 0.12 | 17.0 | 7.0 | -6.0 | 12.0 | 19.1 | 18.0 |
| Cal3 | 1.98 | 0.12 | 0.16 | 18.0 | 11.0 | 12.0 | - | 17.4 | 12.9 |
| Cal4 | 2.82 | 0.18 | 0.28 | 2.0 | 0.0 | -4.0 | 5.0 | -4.4 | -1.9 |
| Cal5 | 4.04 | 0.30 | 0.37 | 7.0 | 4.0 | -1.0 | 5.0 | -6.7 | -4.6 |
| Cal6 | 5.76 | 0.44 | 0.66 | -3.0 | -4.0 | -7.0 | -5.0 | -1.9 | -2.2 |
| Cal7 | 8.24 | 0.65 | 0.83 | 3.0 | 3.0 | 2.0 | 4.0 | -2.9 | -1.8 |
| Cal8 | 11.76 | 0.84 | 1.29 | 0.0 | 1.0 | 3.0 | 4.0 | -2.3 | -2.4 |
| Cal9 | 16.81 | 1.29 | 1.60 | 8.0 | 8.0 | -3.0 | -1.0 | 0.1 | 1.2 |
| Cal10 | 24.01 | 1.67 | 2.66 | 3.0 | 3.0 | 10.0 | 9.0 | 0.3 | -4.1 |
| Cal11 | 34.30 | 3.10 | 4.09 | -20.0 | -18.0 | -15.0 | -16.0 | 2.4 | 5.4 |
| Cal12 | 49.00 | 3.70 | 4.91** | 4.0 | 4.0 | 10.0 | 8.0 | -1.0 | -1.6 |

After applying a linear fit across a range of nominal concentrations that yield the best calculated accuracy of the SHBG concentration, a range of nominal concentrations was found that: yielded a good correlation for all instruments used in validation; covered the range of response ratios expected for the intended use patient population; and yielded bias values within ±20%. The difference between the observed and expected response is divided by the expected response to measure bias as a ratio. There was no systematic bias in the accuracy values and accordingly, the assay was deemed to yield acceptable results across all instruments.

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**Figure 1.** Example Linearity plots for IBP4 and SHBG

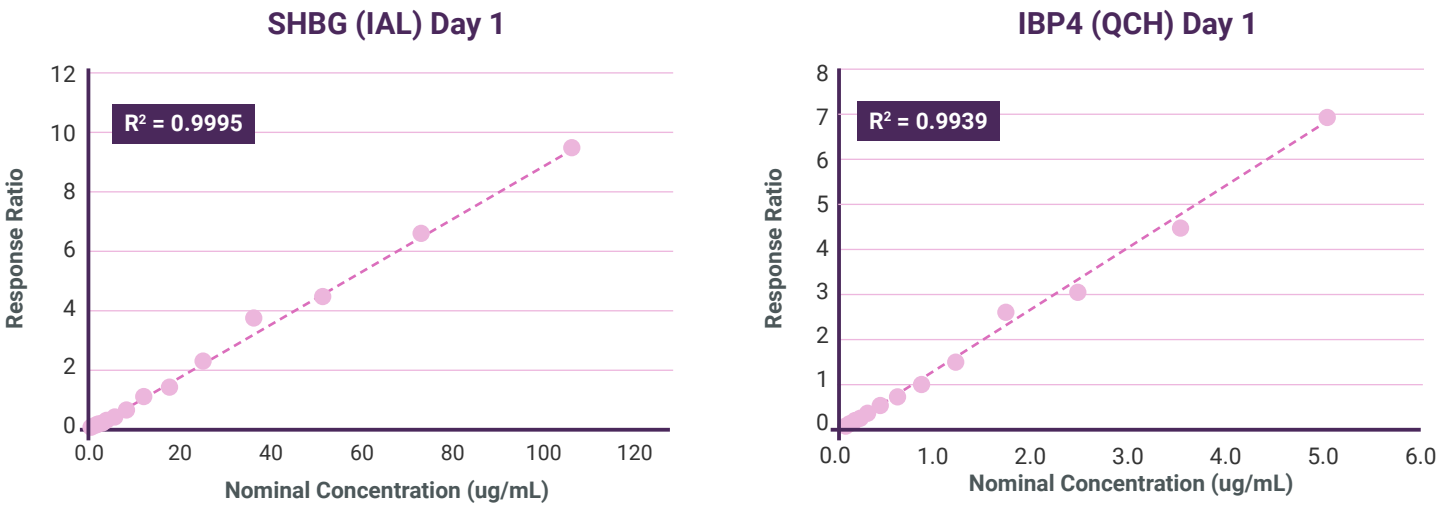


**Table 2.** Linearity test accuracy results for IBP4

Values in green were deemed to meet all linearity acceptance criteria for IBP4.

**Linearity Test Calculated vs. Nominal Concentration Results for IBP4**

| Sample | Nominal Concentration (ug/mL) | Lowest Observed RR *LLOQ | Highest Observed RR **ULOQ | INST 1 Day1 (% bias) | INST 2 Day1 (% bias) | INST 1 Day2 (% bias) | INST 2 Day2 (% bias) | INST 1 Day3 (% bias) | INST 2 Day3 (% bias) |
|---|---|---|---|---|---|---|---|---|---|
| Cal2 | 0.07 | 0.05* | 0.15 | 11.4 | 2.8 | 18.4 | 16.5 | 16.5 | 12.2 |
| Cal3 | 0.10 | 0.08 | 0.19 | 15.4 | 11.0 | 19.5 | - | 18.8 | 6.3 |
| Cal4 | 0.14 | 0.11 | 0.27 | 1.1 | -1.3 | 7.7 | 9.0 | -8.0 | -0.8 |
| Cal5 | 0.20 | 0.20 | 0.34 | 3.0 | 5.5 | 3.6 | 6.6 | -9.9 | -2.1 |
| Cal6 | 0.29 | 0.29 | 0.48 | -3.1 | -2.7 | -5.8 | -5.0 | -6.0 | -0.5 |
| Cal7 | 0.41 | 0.43 | 0.62 | 5.0 | 3.7 | 0.3 | 2.4 | 3.5 | -2.3 |
| Cal8 | 0.59 | 0.53 | 0.93 | 0.7 | 1.6 | 2.5 | 3.3 | -4.4 | 0.4 |
| Cal9 | 0.84 | 0.86 | 1.23 | 7.1 | 6.9 | -2.8 | -2.6 | 2.3 | -1.1 |
| Cal10 | 1.20 | 1.08 | 1.80 | 2.4 | 3.7 | 8.8 | 7.4 | 0.2 | -3.6 |
| Cal11 | 1.72 | 1.86 | 2.80 | -16.9 | -18.1 | - | - | 1.6 | 5.1 |
| Cal12 | 2.45 | 2.38 | 3.39** | 5.5 | 7.2 | 6.7 | 7.8 | -0.8 | -1.5 |

After applying a linear fit across a range of nominal concentrations that yield the best calculated accuracy of the IBP4 concentration, a range of nominal concentrations was found that: yielded a good correlation for all instruments; covered the range of response ratios expected for the intended use patient population; and yielded bias values within ±20%. The difference between the observed and expected response is divided by the expected response to measure bias as a ratio. There was no systematic bias in the accuracy values and accordingly, the assay was deemed to yield acceptable results across all instruments.

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**Table 3.** Signal to background at lower limit of quantitation

| Sample | Instrument 1 | | | Instrument 2 | | |
|---|---|---|---|---|---|---|
| | Average Signal (RR) | Background (UTAK Blank Serum) | Ratio | Average Signal (RR) | Background (UTAK Blank Serum) | Ratio |
| Cal2 | 0.0934 | 0.001 | **93.4** | 0.107 | 0.001 | **107.1** |
| Cal2 | 0.1306 | 0.001 | **130.6** | 0.1253 | 0.001 | **125.3** |

The ratio obtained by dividing the signal obtained at the LLOQ by the background signal was found to be ≥5 times the analyte response at the zero calibrator. Accordingly, the assay was deemed to yield acceptable results across all instruments.

**Table 4.** Imprecision at lower limit of quantitation

| Protein | Sample | Concentration (ug/mL) | INST 1 Day 1 (% CV) | INST 2 Day 1 (% CV) | INST 1 Day 2 (% CV) | INST 2 Day 2 (% CV) | INST 1 Day 3 (% CV) | INST 2 Day 3 (% CV) |
|---|---|---|---|---|---|---|---|---|
| IBP4 | Cal2 | 0.07 | 11% | 3% | 18% | 17% | 17% | 12% |
| SHBG | Cal2 | 1.38 | 17% | 7% | 6% | 12% | 19% | 18% |

**Table 5.** Linearity test linear fit results for SHBG

Both instruments yielded linear correlation coefficients that met acceptance criteria for SHBG linearity.

| Instrument | Correlation Coefficient ($R^2$) | Pass/Fail ($R^2 > 0.99$) |
|---|---|---|
| LCMS03 | 0.9947 | PASS |
| LCMS04 | 0.9942 | PASS |

**Table 6.** Linearity test linear fit results for IBP4

Both instruments yielded linear correlation coefficients that met acceptance criteria for IBP4 linearity.

| Instrument | Correlation Coefficient ($R^2$) | Pass/Fail ($R^2 > 0.99$) |
|---|---|---|
| LCMS03 | 0.9981 | PASS |
| LCMS04 | 0.9982 | PASS |

## Assay Reportable Range

The PreTRM Test is a qualitative assay that reports the risk of spontaneous preterm birth before 37 weeks gestation as either “higher risk” or “not higher risk,” based on a validated decision threshold applied to a proprietary regression of the proteomic score and clinical risk factors. Numeric risk percentages are not reported. The range of proteomic scores observed in validation studies is documented for internal quality control purposes but is not clinically reported. Analytical performance characteristics, including sensitivity, specificity, and predictive values, are provided in the assay validation summary.

# Performance Characteristics

## Analytical Specificity/Interference

Interference and specificity were evaluated by spiking a pooled serum sample derived from our intended use population with two levels of Triglyceride Rich Lipoproteins, conjugated and unconjugated bilirubin, and hemolysate at levels considered clinically high and pathological. No significant shift in the results ($p \geq 0.05$) was detected at any level of interference. Additionally, no level of interference shifted the retention time in a way that prevented specific identification of the target analyte or changed its qualitative to quantitative transition ratio significantly.

## Precision – Intrabatch (Repeatability)

Intrabatch precision was evaluated by testing samples (N = 28 for each sample type) that represented high, low and threshold test results from our intended use population. These samples were analyzed repeatedly within a day to demonstrate that the assay could yield CVs ≤ 20%. Samples were tested for both response ratios and proteomic score, but the score result is used in clinical decision making.

**Table 7.** Within-batch imprecision (repeatability) of analytes by batch

| SAMPLE | Analyte/Score | N | % CV | Pass/Fail |
|---|---|---|---|---|
| High | IBP4 | 28 | 1.1 | Pass |
| | SHBG | 28 | 1.5 | Pass |
| | Score | 28 | 1.5 | Pass |
| Low | IBP4 | 28 | 2.4 | Pass |
| | SHBG | 28 | 1.1 | Pass |
| | Score | 28 | 1.1 | Pass |
| Threshold | IBP4 | 28 | 2.5 | Pass |
| | SHBG | 28 | 1.2 | Pass |
| | Score | 28 | 1.5 | Pass |

The method demonstrated acceptable repeatability.

## Precision – Interbatch (Reproducibility)

Interbatch precision was evaluated by testing samples (N = 294 for each sample type) that represented high, low and threshold test results from the intended use population. These samples were analyzed repeatedly across 21 batches spread over 20 days across all test systems and personnel, to demonstrate that the assay could yield overall CVs of ≤ 20% across that time frame.

**Table 8.** Interbatch imprecision (reproducibility) of analytes

| SAMPLE | Analyte/Score | N | % CV | Pass/Fail |
|---|---|---|---|---|
| High | IBP4 | 294 | 9.2 | Pass |
| | SHBG | 294 | 6.5 | Pass |
| | Score | 294 | 7.7 | Pass |
| Low | IBP4 | 294 | 8.4 | Pass |
| | SHBG | 294 | 6.4 | Pass |
| | Score | 294 | 3.3 | Pass |
| Threshold | IBP4 | 294 | 13.5 | Pass |
| | SHBG | 294 | 4.5 | Pass |
| | Score | 294 | 3.3 | Pass |

The method demonstrated acceptable reproducibility.

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# Performance Characteristics

## LIMITS OF QUANTITATION

The lower and upper limits of quantitation were determined from linearity experiments, in which recombinant IBP4 and SHBG proteins were spiked into blank serum matrix at thirteen known nominal concentrations (Cal1 – Cal13). The upper limit of quantitation (ULOQ) was the highest nominal concentration of each analyte that yielded an acceptable correlation ($R^2$) and had a calculated concentration within 20% of the nominal concentration and had a CV ≤20%. The lower limit of quantitation (LLOQ) met the same criteria but also had a signal-to-background >5.

**Table 1.** Linearity test accuracy results for SHBG

Values in green were deemed to meet all linearity acceptance criteria for SHBG.

| Sample | Nominal Concentration (ug/mL) | Lowest Observed RR *LLOQ | Highest Observed RR **ULOQ | INST 1 Day1 (% bias) | INST 2 Day1 (% bias) | INST 1 Day2 (% bias) | INST 2 Day2 (% bias) | INST 1 Day3 (% bias) | INST 2 Day3 (% bias) |
|---|---|---|---|---|---|---|---|---|---|
| Cal2 | 0.69 | 0.086* | 0.137 | -19.4 | -18.5 | -17.1 | -13.4 | -4.7 | -19.8 |
| Cal3 | 0.99 | 0.122 | 0.188 | -10.9 | -11.4 | -10.5 | -15.7 | 4.9 | -9.0 |
| Cal4 | 1.41 | 0.164 | 0.256 | -8.1 | -9.1 | 3.8 | 7.0 | 2.6 | -4.6 |
| Cal5 | 2.02 | 0.237 | 0.384 | -3.4 | -6.6 | -6.9 | -6.2 | 6.7 | 0.9 |
| Cal6 | 2.88 | 0.319 | 0.574 | -1.6 | -3.0 | -9.0 | -8.8 | 6.3 | 3.2 |
| Cal7 | 4.12 | 0.542 | 0.772 | -0.3 | -4.1 | -0.2 | 0.1 | -4.0 | -5.4 |
| Cal8 | 5.88 | 0.762 | 1.082 | 0.4 | 1.0 | -0.8 | 0.2 | -2.1 | -2.8 |
| Cal9 | 8.40 | 1.095 | 1.565 | -0.7 | -0.2 | 3.1 | 4.0 | -2.3 | -0.3 |
| Cal10 | 12.01 | 1.321 | 2.277 | 1.9 | 2.2 | 1.1 | 0.6 | 0.3 | 2.7 |
| Cal11 | 17.15 | 2.047 | 3.355 | 4.7 | 6.2 | 2.9 | 2.0 | 5.0 | 6.4 |
| Cal12 | 24.50 | 3.200 | 4.700 | -1.7 | -0.8 | 0.6 | 0.0 | -3.3 | -3.2 |
| Cal13 | 35.00 | 4.592 | 6.405** | 0.1 | -1.0 | -1.2 | -0.7 | -0.9 | -0.2 |

After applying a linear fit across a range of nominal concentrations that yield the best calculated accuracy of the SHBG concentration, a range of nominal concentrations was found that: yielded a good correlation for all instruments used in validation; covered the range of response ratios expected for the intended use patient population; and yielded bias values within ±20%. There was no systematic bias in the accuracy values and accordingly, the assay was deemed to yield acceptable results across all instruments.

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# Performance Characteristics

**Figure 1.** Example correlation plots for IBP4 and SHBG

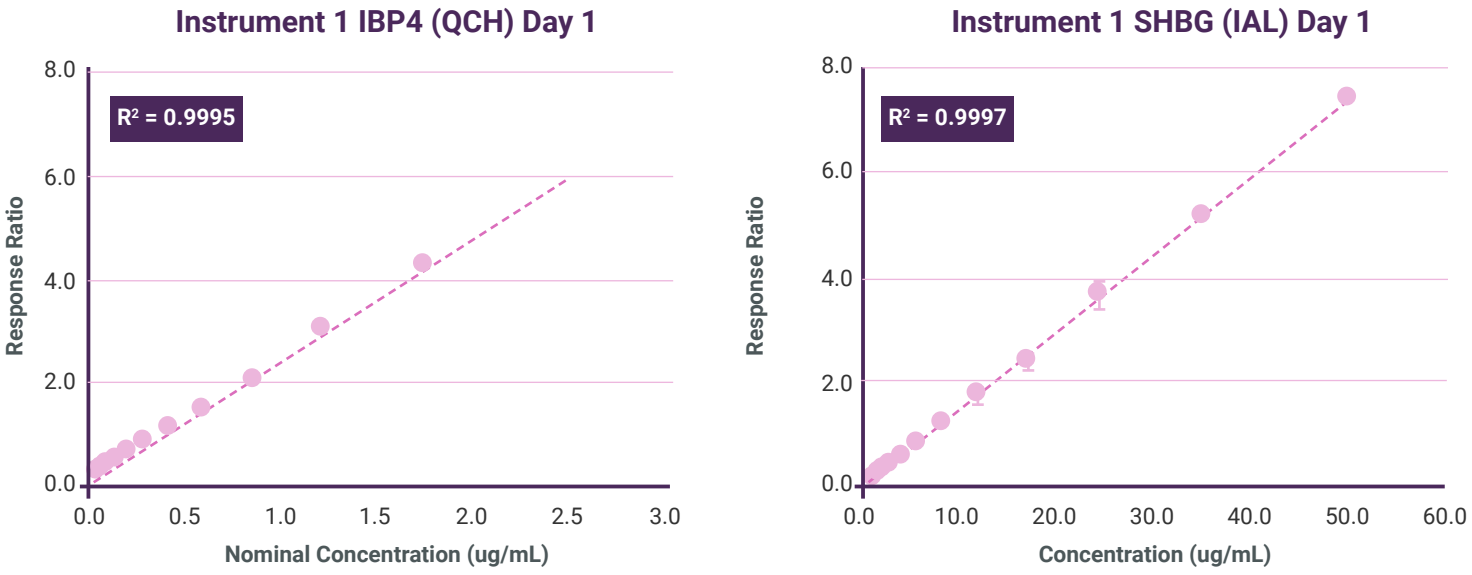


**Table 2.** Linearity test accuracy results for IBP4

Values in green were deemed to meet all linearity acceptance criteria for IBP4.

| Sample | Concentration (ug/mL) | Lowest Observed RR *LLOQ | Highest Observed RR **ULOQ | INST 1 Day 1 (% bias) | INST 2 Day 1 (% bias) | INST 1 Day 2 (% bias) | INST 2 Day 2 (% bias) | INST 1 Day 3 (% bias) | INST 2 Day 3 (% bias) |
|---|---|---|---|---|---|---|---|---|---|
| Cal1 | 0.02 | 0.200* | 0.308 | -16.4 | -15.6 | -14.2 | -19.8 | -3.4 | -11.0 |
| Cal2 | 0.03 | 0.224 | 0.323 | -12.2 | -17.3 | -2.5 | -19.3 | -19.7 | -15.2 |
| Cal3 | 0.05 | 0.246 | 0.351 | 0.6 | -11.7 | -7.7 | -5.9 | 11.6 | -5.5 |
| Cal4 | 0.07 | 0.289 | 0.447 | -5.7 | -10.6 | 16.3 | 6.7 | 3.0 | -13.8 |
| Cal5 | 0.10 | 0.361 | 0.518 | -2.3 | -4.4 | 0.8 | -10.0 | 4.7 | 8.2 |
| Cal6 | 0.14 | 0.421 | 0.679 | 1.5 | -1.9 | -8.7 | -12.9 | 4.6 | 3.7 |
| Cal7 | 0.21 | 0.584 | 0.788 | -2.6 | 0.2 | -0.5 | -1.2 | -4.6 | -4.1 |
| Cal8 | 0.29 | 0.751 | 1.062 | 1.1 | 5.3 | 0.3 | -0.3 | -2.3 | -4.5 |
| Cal9 | 0.42 | 1.087 | 1.393 | 0.9 | -0.6 | 3.9 | 5.3 | -0.4 | -0.6 |
| Cal10 | 0.60 | 1.222 | 2.083 | 0.6 | 0.6 | -0.4 | 1.4 | 0.7 | 3.6 |
| Cal11 | 0.86 | 1.836 | 2.921 | 3.6 | 5.8 | -0.1 | 2.5 | 4.5 | 5.8 |
| Cal12 | 1.23 | 2.922 | 3.838 | -1.9 | -2.7 | -0.7 | 1.5 | -3.4 | -3.9 |
| Cal13 | 1.75 | 3.870 | 5.431** | 0.0 | -0.2 | 0.3 | -1.7 | -0.4 | 0.7 |

After applying a linear fit across a range of nominal concentrations that yield the best calculated accuracy of the IBP4 concentration, a range of nominal concentrations was found that: yielded a good correlation for all instruments; covered the range of response ratios expected for the intended use patient population; and yielded bias values within ±20%. There was no systematic bias in the accuracy values and accordingly, the assay was deemed to yield acceptable results across all instruments.

# Performance Characteristics

**Table 3.** Signal to background ratio at lower limit of quantitation

| Protein | Sample | Instrument 1 | | | Instrument 2 | | |
|---|---|---|---|---|---|---|---|
| | | Average Signal (RR) | Background (UTAK Blank Serum) | Ratio | Average Signal (RR) | Background (UTAK Blank Serum) | Ratio |
| SHBG | Cal2 | 0.106 | 0.001 | **106** | 0.100 | 0.001 | **100** |
| IBP4 | Cal1 | 0.245 | 0.001 | **245** | 0.232 | 0.001 | **232** |

The ratio obtained by dividing the signal obtained at the LLOQ by the background signal was found to be ≥5 times the analyte response at the zero calibrator. Accordingly, the assay was deemed to yield acceptable results across all instruments.

**Table 4.** Imprecision at lower limit of quantitation

| Protein | Sample | Concentration (ug/mL) | INST 1 Day 1 (% CV) | INST 2 Day 1 (% CV) | INST 1 Day 2 (% CV) | INST 2 Day 2 (% CV) | INST 1 Day 3 (% CV) | INST 2 Day 3 (% CV) |
|---|---|---|---|---|---|---|---|---|
| SHBG | Cal2 | 0.69 | 5% | 7% | 9% | 9% | 5% | 7% |
| IBP4 | Cal1 | 0.02 | 5% | 4% | 10% | 10% | 8% | 4% |

**Table 5.** Linearity test linear fit results for SHBG

Both instruments yielded linear correlation coefficients that met acceptance criteria for SHBG linearity.

| Instrument | Correlation Coefficient ($R^2$) | Pass/Fail ($R^2 > 0.99$) |
|---|---|---|
| Instrument 1 | 0.9997 | PASS |
| Instrument 2 | 0.9995 | PASS |

**Table 6.** Linearity test linear fit results for IBP4

Both instruments yielded linear correlation coefficients that met acceptance criteria for IBP4 linearity.

| Instrument | Correlation Coefficient ($R^2$) | Pass/Fail ($R^2 > 0.99$) |
|---|---|---|
| Instrument 1 | 0.9995 | PASS |
| Instrument 2 | 0.9988 | PASS |

## Assay Reportable Range

The PreTRM Test is a qualitative assay that reports the risk of spontaneous preterm birth before 37 weeks gestation as either “higher risk” or “not higher risk,” based on a validated decision threshold applied to a proprietary regression of the proteomic score and clinical risk factors. Numeric risk percentages are not reported. The range of proteomic scores observed in validation studies is documented for internal quality control purposes but is not clinically reported. Analytical performance characteristics, including sensitivity, specificity, and predictive values, are provided in the assay validation summary.

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# Performance Characteristics

## Analytical Specificity/Interference

Interference and specificity were evaluated by spiking a pooled serum sample derived from our intended use population with two levels of Triglyceride Rich Lipoproteins, conjugated and unconjugated bilirubin, and hemolysate at levels considered clinically high and pathological. No significant shift in the results ($p \geq 0.05$) was detected at any level of interference. Additionally, no level of interference shifted the retention time in a way that prevented specific identification of the target analyte or changed its qualitative to quantitative transition ratio significantly.

## Precision – Intrabatch (Repeatability)

Intrabatch precision was evaluated by testing samples (N = 32 for each sample type) that represented high, low and threshold test results from our intended use population. These samples were analyzed repeatedly within a day to demonstrate that the assay could yield CVs ≤ 20%. Samples were tested for both response ratios and proteomic score, but the score result is used in clinical decision making.

**Table 7.** Within-batch imprecision (repeatability) of analytes by batch

| SAMPLE | Analyte/Score | N | % CV | Pass/Fail |
|---|---|---|---|---|
| High | IBP4 | 31* | 1.3 | Pass |
| | SHBG | 31* | 0.9 | Pass |
| | Score | 31* | 4.2 | Pass |
| Low | IBP4 | 32 | 4.4 | Pass |
| | SHBG | 32 | 3.3 | Pass |
| | Score | 32 | 4.0 | Pass |
| Threshold | IBP4 | 32 | 9.0 | Pass |
| | SHBG | 32 | 1.7 | Pass |
| | Score | 32 | 3.3 | Pass |

* One replicate dropped owing to liquid handling issue

The method demonstrated acceptable repeatability.

## Precision – Interbatch (Reproducibility)

Interbatch precision was evaluated by testing samples (N = 96 for each sample type) that represented high, low and threshold test results from the intended use population. These samples were analyzed repeatedly across 12 batches spread over 5 days across all test systems and personnel, to demonstrate that the assay could yield overall CVs of ≤ 20% across that time frame.

**Table 8.** Interbatch imprecision (reproducibility) of analytes

| SAMPLE | Analyte/Score | N | % CV | Pass/Fail |
|---|---|---|---|---|
| High | IBP4 | 95* | 5.3 | Pass |
| | SHBG | 95* | 4.8 | Pass |
| | Score | 95* | 5.5 | Pass |
| Low | IBP4 | 96 | 6.0 | Pass |
| | SHBG | 96 | 5.1 | Pass |
| | Score | 96 | 5.1 | Pass |
| Threshold | IBP4 | 96 | 5.3 | Pass |
| | SHBG | 96 | 2.1 | Pass |
| | Score | 96 | 1.2 | Pass |

* One replicate dropped owing to liquid handling issue

The method demonstrated acceptable reproducibility.

**REFERENCES:** **1.** Martin JA, Hamilton B, et al. Births: Final Data for 2012. National Vital Statistics Report. Centers for Disease Control and Prevention. 2013;62:9. **2.** Saade GR, Boggess KA, Sullivan SL et al. Development and validation of a spontaneous preterm delivery predictor in asymptomatic women. An J Obstet Gynecol May 2016;214(5):633.e1-24. **3.** Bradford C, Severinsen R, Pugmire T, Rasmussen M, Stoddard K, Uemura Y, Wheelwright S, Mentinova M, Chelsky D, Hunsucker SW, Kearney P, Hickok D, Fleischer TC, Ichetovkin I, Boniface JJ, Critchfield GC, Peltier JM: Analytical validation of protein biomarkers for risk of spontaneous preterm birth.

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