# Simoa® YKL-40 (CHI3L1) Advantage PLUS Assay Kit

## HD-X Data Sheet

Item 105796

**Description:** This data sheet summarizes data from the analytical validation performed at Quanterix to characterize performance of the Simoa® YKL-40 Advantage PLUS Assay kit on the Simoa HD-X Analyzer®.

**Matrix Types:** Assay performance and a recommended dilution were evaluated in multiple matrices (Table 1). See the Kit Instructions for sample and dead volume requirements.

**Table 1.** Minimum required dilutions

| | |
|---|---|
| **Matrix Types** | Serum, EDTA Plasma, CSF |
| **Diluted Sample Volume** | 100 uL per measurement |
| **Human Serum Recommended Dilution *** | 3,200x |
| **Human EDTA Plasma Recommended Dilution *** | 3,200x |
| **Human CSF Recommended Dilution *** | 3,200x |

* Sample dilution of 3,200x is a recommended dilution based on determination of the reference range for normal samples; the dilution linearity results are provided.

**Calibration Curve:** The reconstitution volume, assigned concentrations, Limit of Detection (LOD), analytical Upper Limit of Quantification (ULOQ), analytical Lower Limit of Quantification (LLOQ) described here are representative and may vary from kit lot to kit lot (Figure 1). Refer to the Certificate of Analysis (CoA) for lot-specific calibrator concentrations and reconstitution volumes.

**Limit of Quantification (LOQ)**: The analytical LLOQ was determined as the lowest concentration of the analyte in Sample Diluent with a recovery between 80 – 120% and a CV < ±20%. The analytical ULOQ (ULOQ) is the concentration of the highest calibrator. The analytical LLOQ and the analytical ULOQ multiplied by the Recommended Dilution (3200x) yields the functional LLOQ (fLLOQ) and the functional ULOQ (fLLOQ). The LLOQ was experimentally verified for each kit lot. Minor variations in ULOQ between kit lots may be observed where lot matching was performed (Table 2).

**Limit of Detection (LOD):** The LOD was calculated as 2.5 standard deviations above the mean of the background (Cal A) (Table 2).

**Table 2.** LLOQ and LOD

| | Analytical | Functional |
|---|---|---|
| **LLOQ** | 1.0300 pg/mL | Serum (3200x): 3296 pg/mL<br>EDTA Plasma (3200x): 3296 pg/mL<br>CSF (3200x): 3296 pg/mL |
| **ULOQ** | 500 pg/mL | Serum (3200x): 1,600,000 pg/mL<br>EDTA Plasma (3200x): 1,600,000 pg/mL<br>CSF: 1600000 pg/mL |
| **LOD** | 0.2108 pg/mL | N/A |

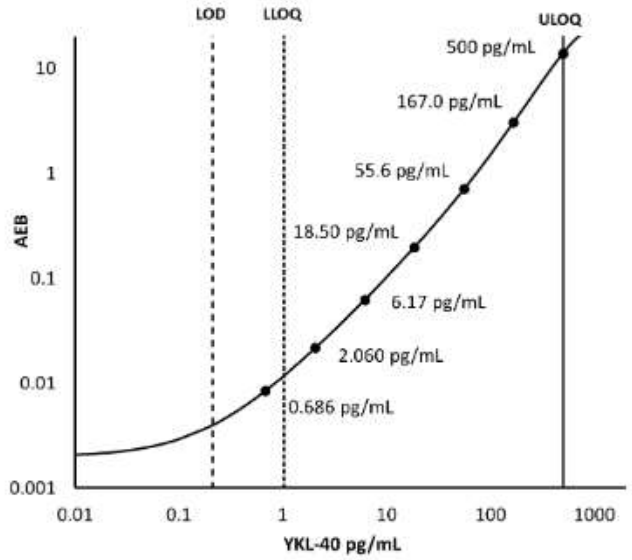


Figure 1. Example calibrator curve

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**Reference Ranges:** Range was established using normal serum (n=20), EDTA plasma (n=20), and CSF (n=20). The mean and median analyte concentrations and the percent of samples above fLLOQ and LOD are reported below (Figure 2 and Table 3).

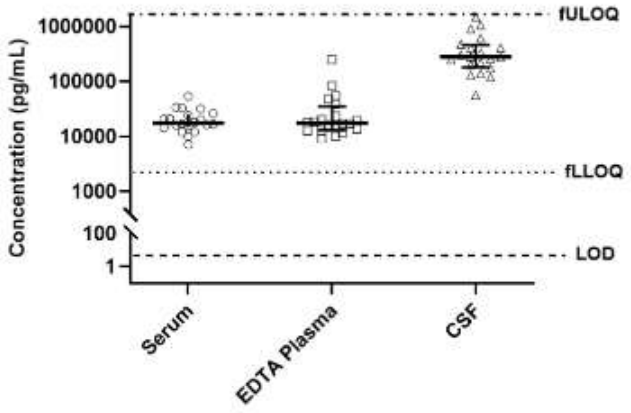


**Figure 2.** Normal sample readings. Bars depict the median with the interquartile range.

**Table 3.** Normal sample readings

| Sample Type | Mean pg/mL | Median pg/mL | % Above LOD | % Above fLLoQ |
|---|---|---|---|---|
| Serum | 21105 | 17590 | 100% | 100% |
| EDTA Plasma | 35726 | 17609 | 100% | 100% |
| CSF | 405486 | 279852 | 100% | 100% |

**Precision:** Precision was calculated using serum, EDTA Plasma, CSF, and assay kit controls diluted to the Recommended Dilution, 3200x (Table 4). Triplicate measurements were made across 12 runs. 2 reagent lots were each tested 3 times on 2 instruments, providing a mean of 36 individual measurements. Four distinct precision values were calculated from the 36 measurements:

1. **Within Run %CV** describes the variability of the %CV within a run, inclusive of 2 reagent lots and 2 instruments.
2. **Run to Run Conc %CV** describes the variability of the concentration value across all 12 runs, inclusive of 2 reagent lots and 2 instruments.
3. **Instrument %CV** describes instrument-to-instrument variability.
4. **Lot %CV** describes lot-to-lot variability.

**Table 4.** Precision

| Sample | Mean (pg/mL) | Within Run %CV | Run to Run Conc %CV | Instrument %CV | Lot %CV |
|---|---|---|---|---|---|
| Control 1 | 159 | 9.2% | 13.0% | 1.8% | 8.3% |
| Control 2 | 7972 | 3.0% | 7.0% | 0.3% | 4.7% |
| Serum 1 | 19848 | 5.9% | 8.1% | 0.8% | 2.7% |
| Serum 2 | 684415 | 4.5% | 8.0% | 3.5% | 2.2% |
| Plasma 1 | 20501 | 5.4% | 7.2% | 0.4% | 2.9% |
| Plasma 2 | 808203 | 4.0% | 9.2% | 1.0% | 3.7% |
| CSF 1 | 108609 | 5.5% | 8.9% | 0.0% | 4.4% |
| CSF 2 | 123109 | 4.2% | 8.7% | 1.1% | 3.8% |

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**Spike Recovery:** Percent recovery was calculated as the difference between the spiked (with antigen) sample and the un-spiked sample, relative to the spiked (with antigen) Sample Diluent (Table 5).

**Linearity:** Human serum, EDTA plasma, and CSF samples were diluted 3200x serially with Sample Diluent. Linearity refers to the assay's ability to produce proportional and accurate results across a defined dilution range. Linearity was assessed by performing serial dilutions of samples diluted with Sample Diluent (Table 5).

**Table 5.** Spike Recovery and Linearity

| | |
|---|---|
| **Spike Recovery (serum)** | **Mean 97.1 %** range 78.0 – 105.4% |
| **Spike Recovery (EDTA plasma)** | **Mean 101.0 %** range 93.5 – 116.1% |
| **Spike Recovery (CSF)** | **Mean 94.3 %** range 85.9 – 104.6% |
| **Linearity Mean (SD) (serum, Linear Range 800x – 6400x)*** | **Mean 100.0 %** range 69.0 – 162.1% |
| **Linearity Mean (SD) (EDTA plasma Linear Range 800x – 6400x)*** | **Mean 120.0 %** range 73.3 – 277.7% |
| **Linearity Mean (SD) (CSF, Linear Range 800x – 25600x)*** | **Mean 100.0 %** range 82.8 – 143.9% |

* The data provided for Dilution Linearity includes dilutions less than 3200x since the 3200x dilution is a recommended dilution, not a minimum required dilution (MRD).

The Simoa® YKL-40 Advantage PLUS assay kit is formulated for use on the Simoa HD-X Analyzer®. Validation results for the Simoa HD-X Analyzer® are summarized in this data sheet.

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