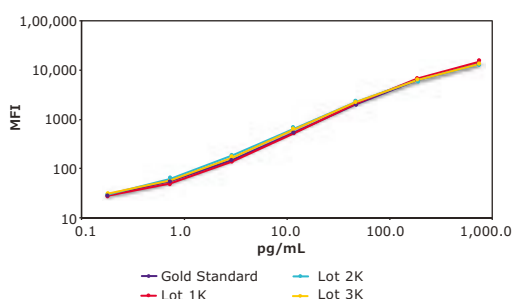


Quality Differentiates Every MILLIPLEX® Assay

MILLIPLEX® Lot-to-Lot Reproducibility

We take measures to ensure consistent results for samples across kit lots

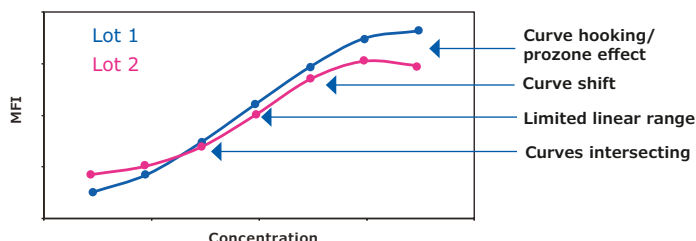
HSTCMAG-28SK, Human IL-6 Standard Curves
Lot-to-Lot Comparison



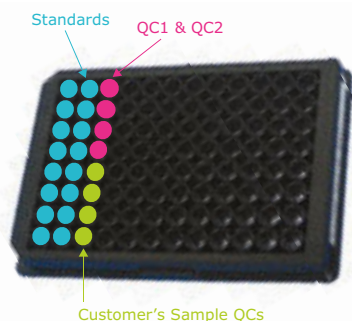
Standard Curves Checked for Each Analyte Across Kit Lots

- Standard dilution curve is used to calibrate each assay
- Gold standard
 - Gold standard specifications set during assay development
 - For each new lot of standard, curve potency is compared to the designated gold standard lot and must pass internal acceptance criteria
 - Potency trend charts maintained for all standard curves
- Assay sensitivity in samples is periodically tested
- Example: Gold Standard lot compared to three subsequent lots (1K-3K) of the analyte Human IL-6 for Cat. No. HSTCMAG-28SK

The Importance of Standard Curve Potency



Analyte standard curves from all lots should overlap as closely as possible. Maintaining curve potency acceptance criteria helps avoid common problems which negatively impact calculation of analyte concentration in samples. Problematic standard and component lots are never released for sale.



Controls to Verify Assay Performance

- Each kit includes quality controls (QC1 and QC2), low and high dilutions of recombinant proteins for each analyte
- Assay results for these QCs should be checked against the provided Quality Control Range Sheet values to ensure proper pipetting and assay setup has been accomplished
- Trend charts are maintained for QC ranges across lots (accessible on request)
- We recommend the customer include experiment relevant sample QCs in each assay

MILLIPLEX® kits are manufactured in facilities which are ISO 9001-2015 compliant and are for research use only (RUO), not for use in clinical or for medical diagnostic purposes.



MILLIPLEX® Assay Development

We set and define our MILLIPLEX® assay specifications during kit development. Verification data is provided in each kit protocol. Every MILLIPLEX® kit includes all the optimized reagents and instructions needed to run the assay and read the assay plate on your Luminex® instrument.

Assay Specifications

Antibody selectivity, specificity and cross-reactivity: Test each antibody for detection of other analytes within the same panel*; test species cross-reactivity**

Gold standard: Reference calibrator specifications defined

Standard curve range*: Concentration for each standard dilution

Sensitivity*: Minimum detectable concentration (MinDC+2SD) or LOD

Precision of control standards*: Intra-assay within 15% CV (SD/Mean)
Inter-assay within 20% CV (SD/Mean)

Accuracy*: % recovery of standards in serum matrix; range 70-130%

Dilution linearity:** % recovery of diluted samples, un-spiked and spiked with standard; range 70-130%

Validated sample types*: Typically serum, plasma, tissue/cell culture; for specific kits, CSF or urine

Sample testing:** For biological relevance, detection of analyte within range of assay

Sample dilution*: Optimized for all analytes within each kit

Serum matrix*: An optimized proprietary serum matrix is developed for each kit where a matrix effect has been observed upon spike/recovery analysis; added to standards when assaying serum/plasma samples in order to simulate sample environment

Consistent performance:** Whether assayed in multiplex or singleplex

Stability testing*: For shipping and storage of kit components; premixed beads; sample/analyte freeze/thaw cycles

Quality controls and QC ranges*:** Recombinant protein at two dilutions are run in repeat assays to establish a target QC range; used to verify assay performance compared to kit specifications; user should include experiment-specific QC sample controls in assay

* Kit Protocol ** Contact Technical Support *** Kit Insert

Let MILLIPLEX® be your strategic partner for protein biomarker studies

Plan your project with us so we can work to meet your needs. Let's discuss:

- Assay verification requirements
- Custom assay needs
- Supply chain planning
- Quality agreements
- Packaging/shipping needs
- Reagent change notifications

Visit SigmaAldrich.com/milliplex for more information



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To place an order or receive technical assistance

Order/Customer Service: SigmaAldrich.com/order

Technical Service: SigmaAldrich.com/techservice

Safety-related Information: SigmaAldrich.com/safetycenter

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