ASSURANCE™
INTERFERENCE TEST KIT

Sun Diagnostics

Evaluating RF and HAMA Interference
Recommended Testing Protocol

ASSURANCE™ RF and ASSURANCE™ HAMA from Sun Diagnostics, LLC are designed to simplify the evaluation of assays for interference from Rheumatoid Factor (RF) and Human Anti-Mouse Antibodies (HAMA). This recommended testing protocol is intended to guide the user through their RF and/or HAMA interference testing and assist them in interpreting their data.

1. For each interferent being evaluated, prepare three samples for testing:
    a. Prepare 1:1 dilution of Interferent (RF or HAMA) and diluent.
    b. Prepare a 1:1 dilution of sample and diluent. This is your CONTROL sample.
    c. Prepare a 1:1 dilution of sample and interferent (RF or HAMA). This is your TEST sample.

2. Assay:
    a. Assay each of the prepared samples using the method(s) or assay(s) being evaluated.

3. Evaluate:
    a. Enter your appropriate data into the accompanying spreadsheet. We recommened using ½ of the Total Allowable Error (TEa) as the Dmax (allowable difference allowed)
    b. Review the output of the calculations.
    c. The expected value is the mean of the CONTROL Sample (1b).
    d. The Test result needs to be adjusted for any endogenous analyte present in the RF or HAMA material. The adjusted test result is calculated as 1c-1a.

For Technical Assistance or Support –

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