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User Defined Assay Reference Guide

VITROS® 5,1 FS Chemistry System

Ortho Clinical Diagnostics

VITROS®

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IMPORTANT

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Revision History

Revision Date	Description
2013-12-01	• Changed the date on all pages. • Removed “Johnson & Johnson” from the address on the back cover. NOTE: These changes are not noted by change bars.
2011-11-15	• Changed the date on all pages. • Added IMPORTANT statement about reporting system errors to Customer Technical Services to the “Introduction” on page 1-2.
2011-10-05	• Updated the company logo. • Changed the date on all pages. NOTE: These changes are not noted by change bars.
2009-05-08	• Changed the design of the title page. • Changed from REF number to Pub. No.on title page and footers. • Updated the Revision History and reordered the information for ease of use.
2005-11-30	• Added new Appendix D: Molar Extinction Coefficient. • Added Note and link to new Appendix D on page 2-22. • Updated Revision History for this release. • Regenerated Table of Contents for this revision.
2005-06-15	• First release of document

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1: User Defined Assays

Introduction

The User Defined Assay (UDA) feature of the VITROS 5,1 FS Chemistry System allows you to expand the assay menu beyond those assays currently available from Ortho-Clinical Diagnostics, Inc (OCD). Using the UDA feature, you can program assay protocols using pre-formatted assay templates and reagents from other vendors, or you can define your own protocols.

UDAs use the VITROS MicroTip Special Chemistry processing center. This processing center is equipped with a thermally controlled reagent supply for on-system reagent storage (at 9°C ± 2°C), a metering system capable of delivering precise and accurate sample and reagent volume, an incubator (at 37°C), and a photometer with 12 wavelengths.

The system supports enzymatic, colorimetric, and turbidimetric assay methodologies. You can use serum, plasma, urine, cerebrospinal fluid, and whole blood hemolysate samples. Sample dilution and pre-dilution are supported for these sample types. OCD provides empty reagent packs to be filled with your reagents.

Multiple calibration models (linear regression, cubic spline, Logit/Log4 and Logit/Log5) are available. The UDA feature is supported by all of the current capabilities of the VITROS 5,1 FS Chemistry System that ensure quality results for assays, including:

1. Sample clot detection
2. Sample integrity checks
3. Calibration checks: replicate range, monotonicity, variability of response
4. Optical quality of reaction cuvettes
5. Antigen excess/substrate depletion checks

WARNING: ***ORTHO-CLINICAL DIAGNOSTICS INC. EXPRESSLY DISCLAIMS ALL WARRANTIES WITH RESPECT TO USER-DEFINED METHODS WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.***

WARNING: ***Since Ortho-Clinical Diagnostics does not manufacture or otherwise control the reagents that may be used in the VITROS UD Reagent Pack, the warranty for the VITROS 5,1 FS Chemistry System does not extend to the performance of user-defined reagents (including user-defined test results or standard VITROS 5,1 FS Chemistry System test results that are affected by user-defined testing), their effect on the system operation and types and frequency of maintenance, or their effect on operator safety. The user assumes full responsibility for the selection of the proper reagents, entering the proper test parameters, use of the proper test***

protocol, correctness of the test results, and any associated errors or omissions. Each laboratory must establish specific UDA test performance characteristics in compliance with applicable laws and regulations before performing tests and reporting patient results for diagnostic purposes. The user assumes full responsibility for any local or regional regulatory requirements resulting from the use of user-defined reagents on the VITROS 5,1 FS Chemistry System.

WARNING: ***All fluids used on the system are disposed of in an on-board waste container. Use of reactive chemicals may create a hazard to the operator.***

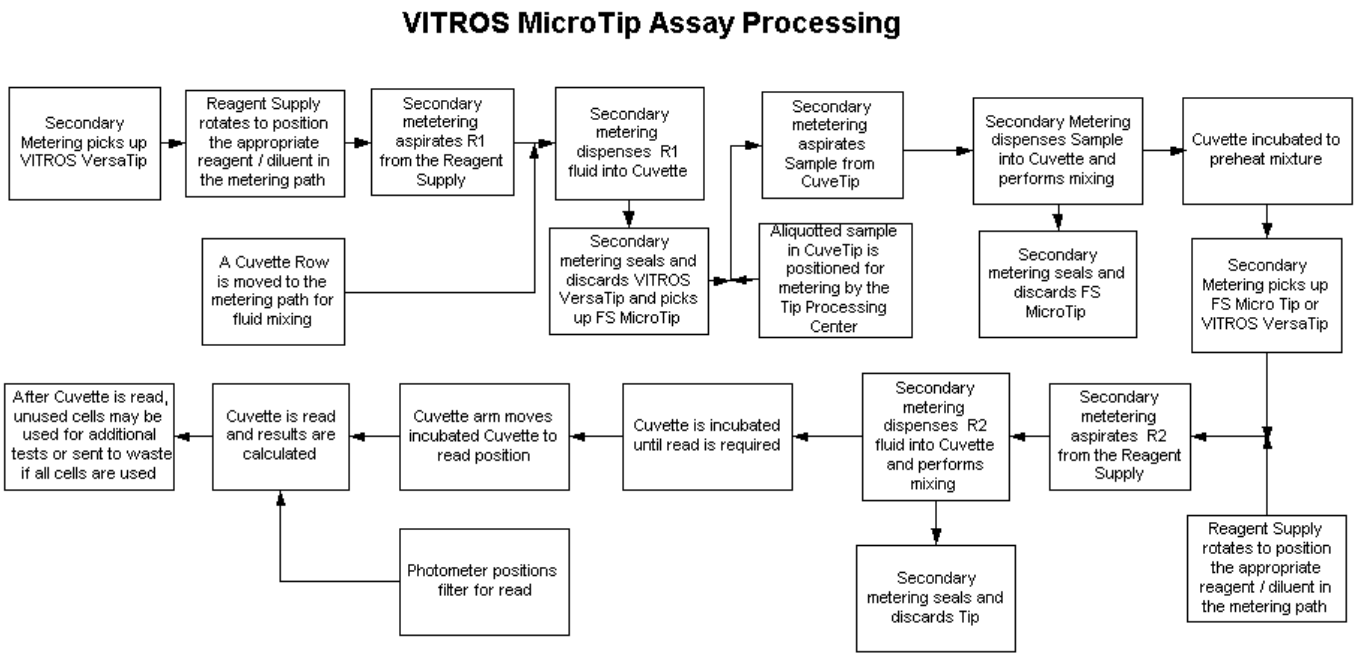
IMPORTANT: Report all VITROS® *System errors generated when processing Research Use Only (RUO) Reagents to Customer Technical Services at Ortho Clinical Diagnostics, Inc.*

VITROS MicroTip Assay Processing

The VITROS 5,1 FS Chemistry System can process discrete photometric assays and perform automatic dilutions using an aliquot of sample from primary collection tubes.

In the VITROS 5,1 FS MicroTip Special Chemistry Center, dispensed volumes of liquid reagent and sample are mixed in a cuvette and incubated for a specified time interval. A second reagent, if required, is added, and absorbance measurements are performed at preselected time intervals. The absorbance measurement is converted to concentration by an appropriate math model and associated calibration. Data is processed using a user-selected algorithm.

Refer to the following diagram for an example of MicroTip processing:



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2: Working with User Defined Assays

Defining a User Defined Assay

1. Complete the User Defined Assay Worksheet
2. Define the New Assay
3. Define the Dilution Parameters
4. Define the Result Parameters
5. Define the Protocol Parameters
6. Define the Calibration Parameters
7. Define the Triple Read Parameters
8. Define the Reagent Lot
9. Fill and Load Reagent Packs

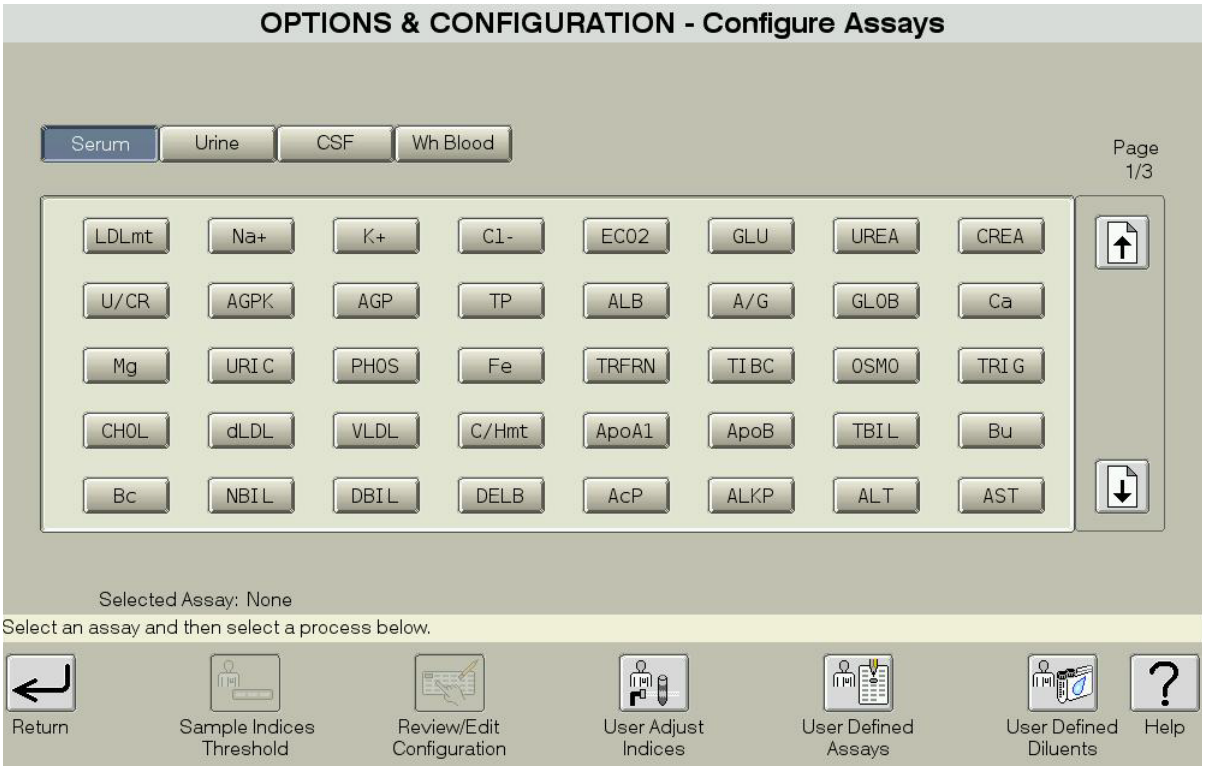
Step 1: Complete the User Defined Assay Worksheet

Using the vendor-supplied application sheet or your own assay protocol information, complete the User Defined Assay Worksheet. See Appendix B:

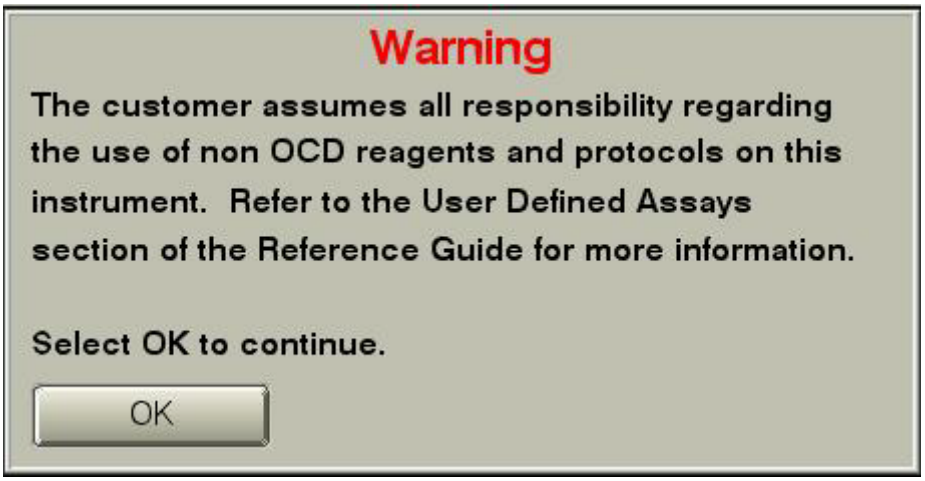
Step 2: Define a New Assay

NOTE: Define the sample indices threshold limits. Please refer to the V-Docs Reference Guide for more information.

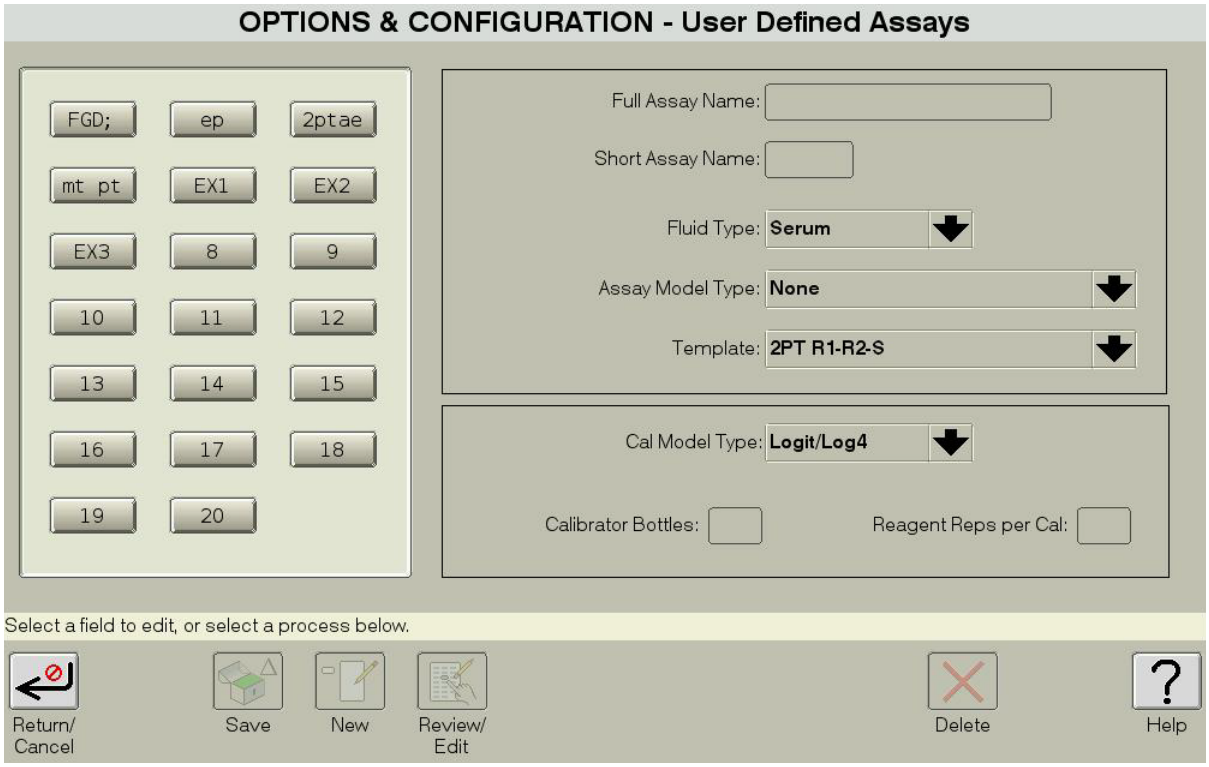
1. Touch Options.
2. On the Options and Configuration screen, touch Configure Assays.



3. On the Configure Assays screen, touch the User Defined Assays button.



4. Touch OK to indicate that you accept responsibility for using non-OCD reagents on the system and to continue.



5. On the User Defined Assays screen, touch one of the 20 assay buttons to begin defining a UDA.

   NOTE: By default, the user-defined assay buttons are named “1” through “20.” The number below the button is the assay id that may be uploaded to the LIS system. LIS codes range from 980 to 999.

6. Touch the New button.

7. Type a full assay name (max. 20 characters). This name displays on the Patient Report.

   NOTE: Max. 20 characters with no restrictions on input values.

8. Type a short assay name (max. 5 characters) for the new UDA. The short name is used to identify this assay throughout the system.

   IMPORTANT: The short assay name must be distinct from existing OCD or other user-defined assay short names. The system checks for assays that are supported by OCD or already defined UDAs.

9. Select a fluid type from the drop down list. Available options are:
   - Serum/Plasma
   - Cerebrospinal Fluid (CSF)
   - Urine
   - Whole blood (hemolysate only)

10. Select an assay model type. The assay model type specifies when and how many photometric readings are taken. Your selection is used to populate the list of templates available in the next step. Available options are:
    - None — select this option if you are unsure of the assay model and would like to view all of the available templates in the next step.
    - Two-point Rate — The system takes two readings, one at the beginning of the reaction, and one at the end of the reaction.
    - Two-point with Antigen Excess Rate Check — A two-point rate with an additional early read to check for Antigen Excess.
    - End Point — The system takes a single reading at the end of the reaction and incubation period, with an optional blank.
    - Multi-point Rate — The system takes a number of user-definable reads during the reaction, with an optional antigen excess check.

11. Select a protocol template from the available options. The protocol template is a set of default values for an assay model type and protocol. Templates are loaded onto your system through the ADD. Any previously defined UDA also displays as a template. This allows you to define a new user defined assay using the specific information from an existing UDA as a starting point.

Template Name	Assay Model	Protocol Steps
EPT1 R1-S	End Point	• Reagent Addition • Optional Blank Read • Sample Addition • End Point Read

Template Name	Assay Model	Protocol Steps
EPT1 R1-S-R2	End Point	• 1st Reagent Addition • Sample Addition • Optional Blank Read • 2nd Reagent Addition • End Point Read
EPT1 R1-R2-S	End Point	• 1st Reagent Addition • 2nd Reagent Addition • Optional Blank Read • Sample Addition • End Point Read
EPT2 R1-S	End Point	• Reagent Addition • Sample Addition • Optional Blank Read • End Point Read
EPT2 R1-S-R2	End Point	• 1st Reagent Addition • Sample Addition • 2nd Reagent Addition • Optional Blank Read • End Point Read
EPT2 R1-R2-S	End Point	• 1st Reagent Addition • 2nd Reagent Addition • Sample Addition • Optional Blank Read • End Point Read
2PTAE R1-S	Two Point Rate with Antigen Excess Rate Check	• Reagent Addition • Sample Addition • Early Rate Read • 1st Rate Read • 2nd Rate Read
2PTAE R1-S-R2	Two Point Ratewith Antigen Excess Rate Check	• 1st Reagent Addition • Sample Addition • 2nd Reagent Addition • Early Rate Read • 1st Rate Read • 2nd Rate Read

Template Name	Assay Model	Protocol Steps
2PTAE R1-R2-S	Two Point Rate with Antigen Excess Rate Check	• 1st Reagent Addition • 2nd Reagent Addition • Sample Addition • Early Rate Read • 1st Rate Read • 2nd Rate Read
2PT R1-S	Two Point Rate	• Reagent Addition • Sample Addition • 1st Rate Read • 2nd Rate Read
2PT R1-S-R2	Two Point Rate	• 1st Reagent Addition • Sample Addition • 2nd Reagent Addition • 1st Rate Read • 2nd Rate Read
2PT R1-R2-S	Two Point Rate	• 1st Reagent Addition • 2nd Reagent Addition • Sample Addition • 1st Rate Read • 2nd Rate Read
NPT R1-S	Multiple Point Rate	• Reagent Addition • Sample Addition • 1st Rate Read • 2nd Rate Read … • 12th Rate Read
NPT R1-S-R2	Multiple Point Rate	• 1st Reagent Addition • Sample Addition • 2nd Reagent Addition • 1st Rate Read • 2nd Rate Read … • 12th Rate Read

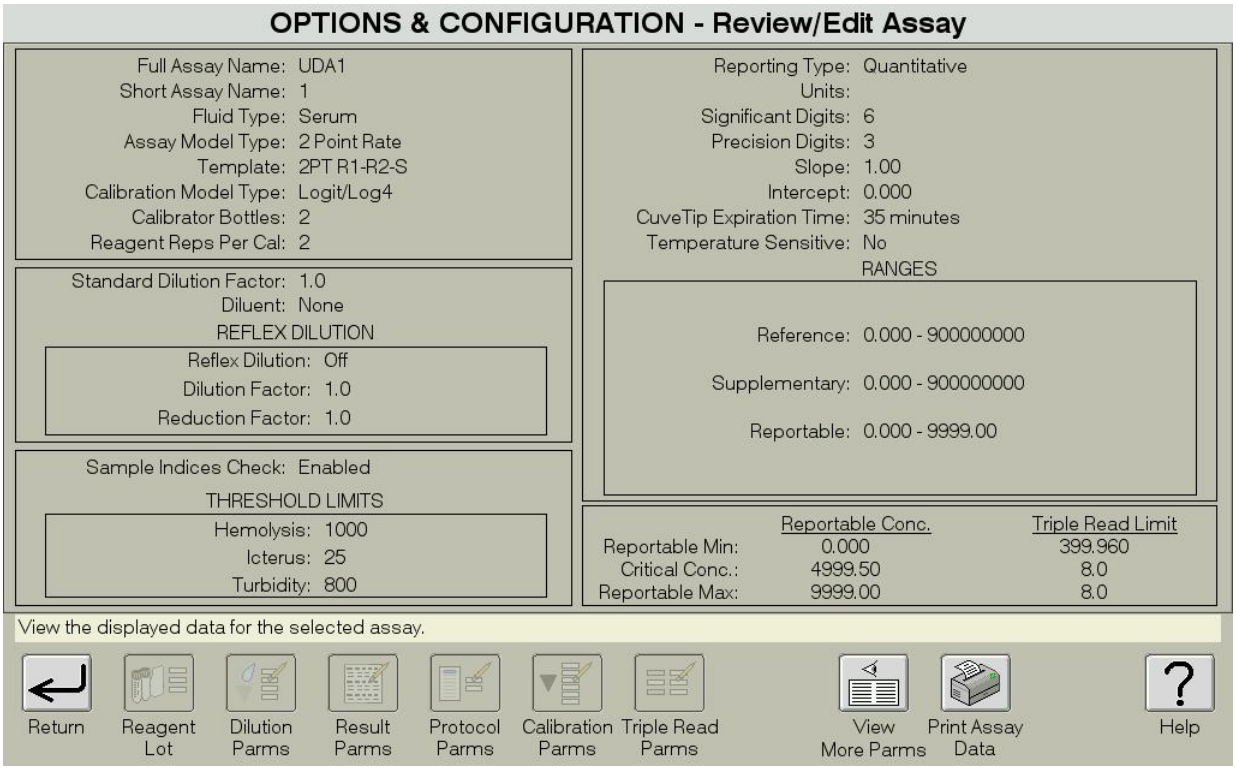
Template Name	Assay Model	Protocol Steps
NPT R1-R2-S	Multiple Point Rate	• 1st Reagent Addition • 2nd Reagent Addition • Sample Addition • 1st Rate Read • 2nd Rate Read … • 12th Rate Read

12. Select a calibration model type from the available options. You can select up to six calibration levels for each UDA, and can program and store the concentration levels for each calibrator. Calibration models are as follows:
    - Linear Regression (2 – 6 calibrator levels)
    - Cubic Spline (4 – 6 calibrator levels)
    - Logit/Log4 (5 – 6 calibrator levels)
    - Logit/Log5 (6 calibrator levels)
13. Type the number of calibrator bottles (levels) (1–6) used for this assay.
14. Type the number of replicates (1–40) for each calibrator level required for the assay calibration.

15. Touch the Save button

    NOTE: Once a UDA is configured and saved, it is available for use in any capacity on the system. UDA's, once programmed, are included as part of a normal system backup.

16. Touch Review/Edit Assay to display the first of three Review/Edit Assay screens.



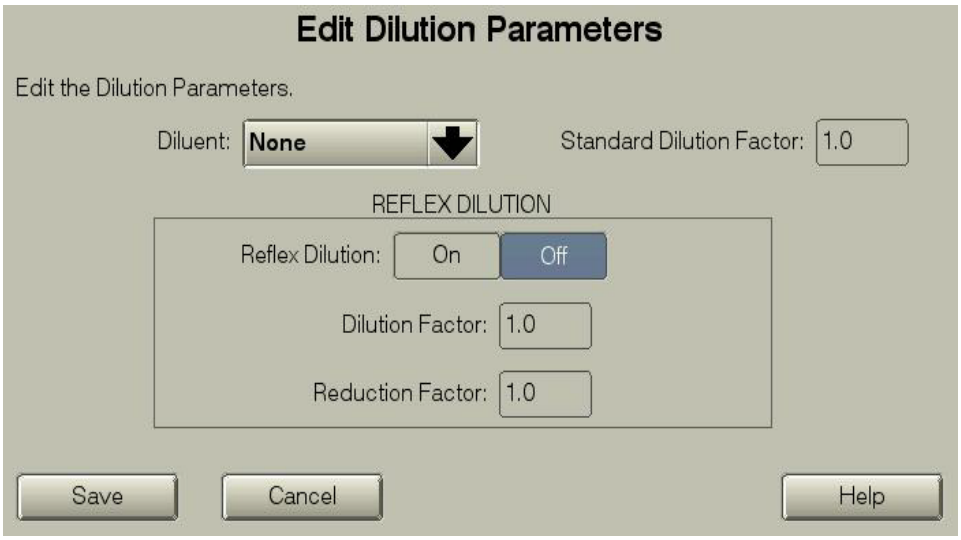
These screens show details of the UDA based on the calibration model type, assay model type, and template selected.

Step 3: Configuring Dilution Parameters

1. Touch Dilution Parms at the bottom of the Review/Edit Assay screen.

   NOTE: For a user defined diluent to appear on the drop-down list, you must first define it. See “Defining a New User Defined Diluent” on page 2-38 later in this document for more information.

WARNING: ***If changing an existing UDA diluent or dilution factor, consider recalibration of the assay.***



2. Select a diluent from the available options. Diluents are loaded onto your system through the ADD and any previously user defined diluents display as available selections. Available diluents are:
   - Saline
   - BSA
   - Water
   - Specialty
   - UED
   - ApoDiluent
   - User Defined Diluents
3. Type a new value for the standard dilution factor. This is the value used to calculate a result when a sample is diluted with a diluent prior to analysis. For example, a standard dilution factor of 5 is 1 part sample and 4 parts diluent. Supported dilution factors are 1, 1.3 – 100, where 1 is an undiluted sample.
4. If you wish to enable reflex dilution, touch On. Reflex dilution enables the system to automatically dilute and re-assay samples with out-of-range results.
5. Type a reflex dilution factor. This reflex dilution factor will be used for samples requiring dilution at reflex metering station.

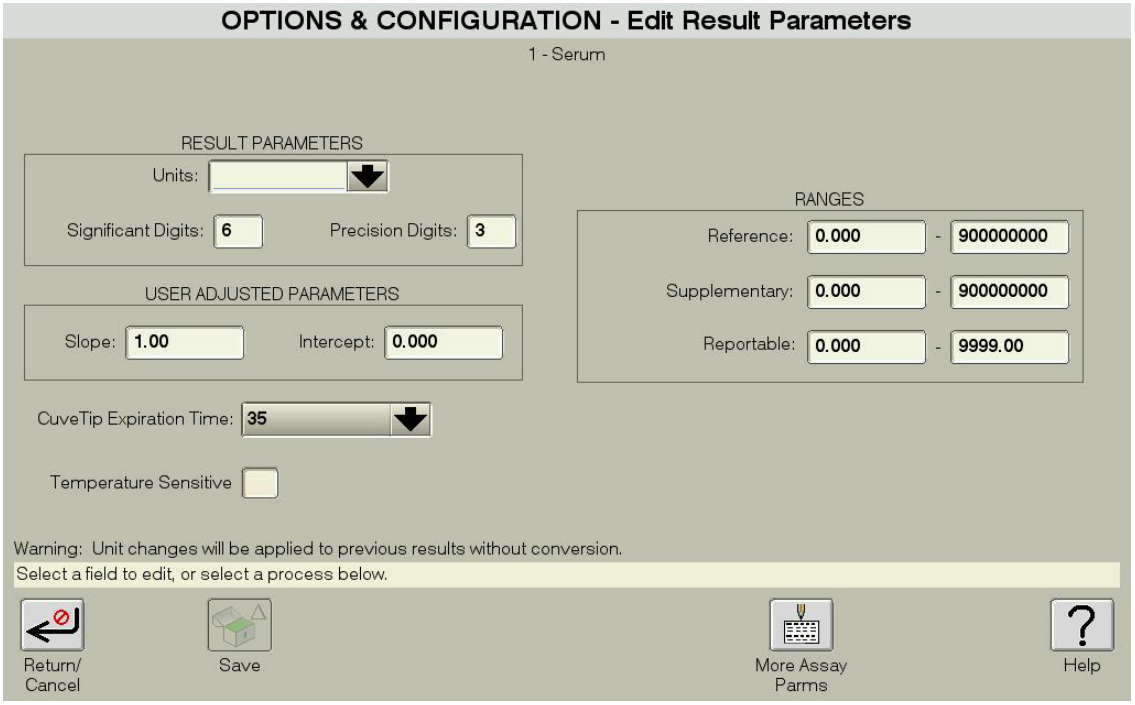
6. Type a reduction factor. The reduction factor is used to reflex test results that are below the reportable range. The standard dilution factor is multiplied by the reduction factor (valid entries 0.2 - 1.0). The resulting reflex dilution will be less than the standard dilution factor but must still be greater than 1.3. (Standard Dilution Factor · Reduction Factor = Dilution Factor for Reflex Test)

   NOTE: This is only applicable if the protocol includes pre-dilution of sample. The reduction factor will allow a smaller pre-dilution factor.

7. Touch Save.

Step 4: Configure Result Parameters

1. Touch Result Parms at the bottom of the Review/Edit Assay screen.



2. In the Result Parameters section of the screen, touch the Units pulldown and select a unit type from the list, or type the units into the box (max. 8 characters).

WARNING: ***Changing units of an existing UDA affects previous results. Previous results in the old units are not converted and no longer display correctly.***

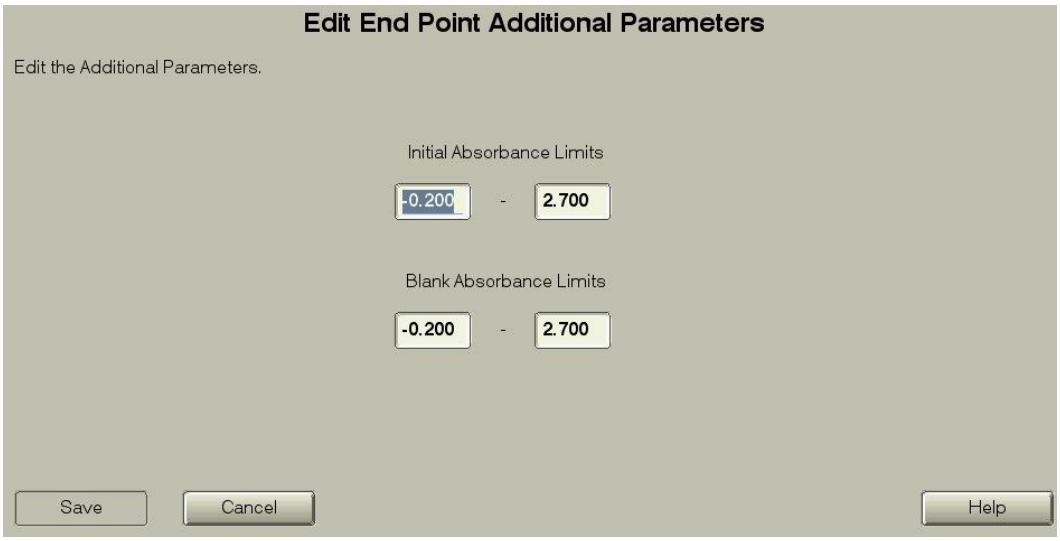
3. Enter the number of significant digits, the maximum number of digits (1–6) that display for all results and numerical data.
4. Enter the number of precision digits, the maximum number of digits (0–3) that display to the right of the decimal point.

   IMPORTANT: The number of precision digits must be less than or equal to the number of significant digits.

5. Type the slope necessary to correlate to the comparative method.
6. Type the intercept necessary to correlate to a comparative method. The intercept is the mathematically established value of the observed result for method ‘y’ when the result determined by method ‘x’ equals zero. The intercept value may be negative or positive.

7. Select a time from the CuveTip Expiration Time available options. This is the amount of time a CuveTip sample can remain in the CUVETIP RING for this particular User Defined Assay before it is flagged as expired. Default is 35 minutes and minimum is 5 minutes. You can determine this number by considering the following factors: the approximate amount of time that a small amount of your sample can remain stable, considering sample volatility and the affects of temperature and humidity on the sample's stability. When you set a shorter expiration time, you affect the priority of processing of this sample within the system. However, if the system is very busy or other tasks are queued as stat, you risk the possibility that your sample will be flagged by the system as expired before it can be processed.
8. Touch the Temperature Sensitive check box, if required. The temperature sensitive assays option improves the precision of temperature sensitive assays by restricting the cells within a cuvette row that can be used. Although precision may be improved, throughput may be reduced.
9. Type the upper and lower values for the reference range. The reference range defines the highest and lowest amounts of the analyte found in an apparently healthy population. Also referred to as "Normal Range."
10. Type the upper and lower values for the supplementary range. The supplementary range is the operator-defined limits, outside or equal to the Reference Range, for results that may require immediate attention and/or action by the laboratory.
11. Type the upper and lower values for the reportable range. The reportable range defines the lowest and the highest amount of the analyte that an assay protocol is capable of predicting. Also referred to as the calibration range or linear range.
12. Touch the Save button.

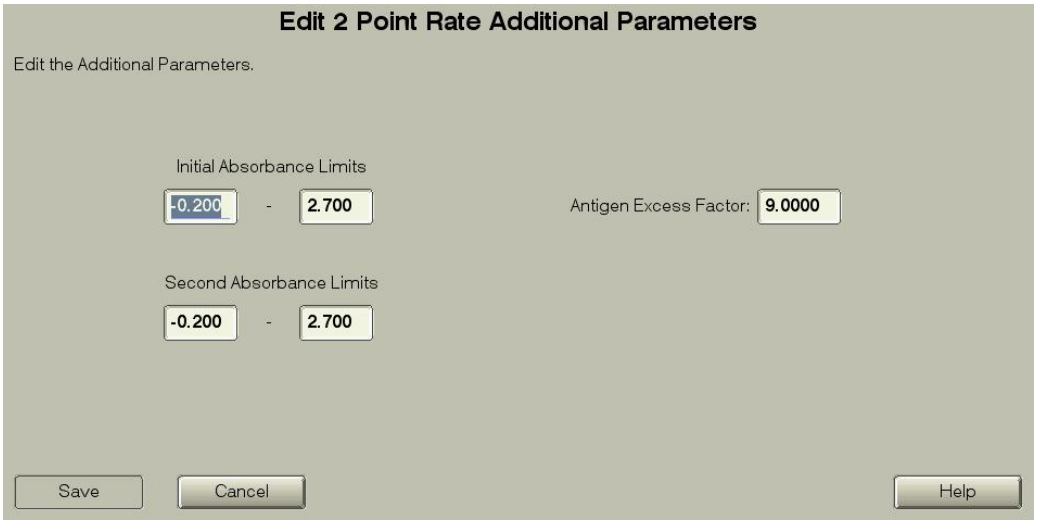
13. Touch the More Assay Parms button to configure additional parameters. The Additional Parameters dialog that displays depends on the selected assay's model type: Two-point Rate, Two-point with Antigen Excess Rate Check, End-point, and Multi-point.
    - If you previously selected End Point as the assay model type, the following dialog displays when you touch the More Assay Parms button.



    a. Edit the following parameters for this assay:
        - Initial Absorbance Limits — Range of values expected at the assay's end point read to determine whether it is within the expected assay range. Values for each field are -0.2 – 2.7. Field length (including sign): 6 characters. Significant digits: 4. Precision digits: 3.
        - Blank Absorbance Limits — Range of values expected at the assay's blank read to determine whether it is within the expected assay range. Values for each field are -0.2 – 2.7. Field length (including sign): 6 characters. Significant digits: 4. Precision digits: 3.

    b. Touch Save to save the parameters and return to the Edit Results Parameters screen.

- If you previously selected 2 Point Rate as the assay model type, the following dialog displays when you touch the More Assay Parms button.

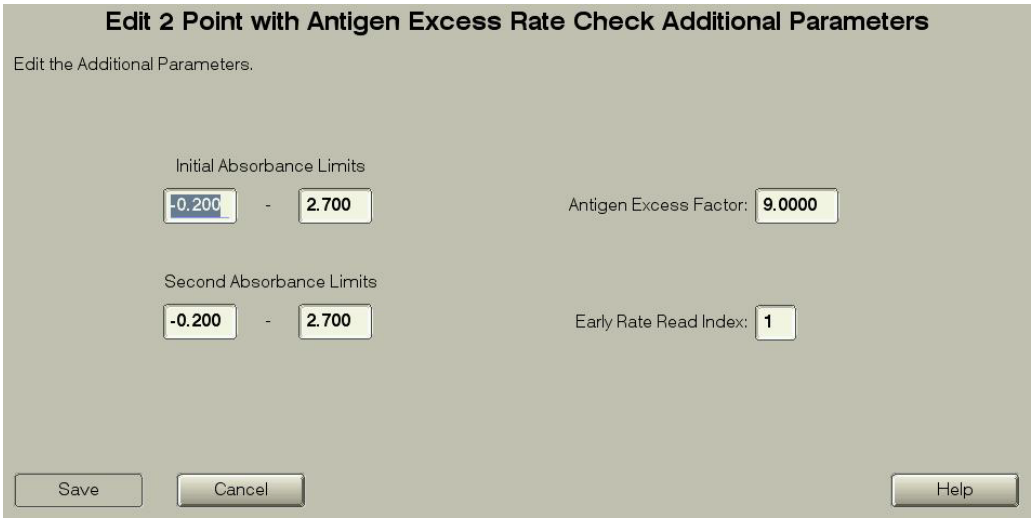


a. Edit the following parameters for this assay:
   - Initial Absorbance Limits — Range of values expected at the assay's first read to determine whether it is within the expected assay range. Values for each field are -0.2 – 2.7. Field length (including sign): 6 characters. Significant digits: 4. Precision digits: 3.
   - Second Absorbance Limits — Range of values expected at the assay's second read to determine whether it is within the expected assay range. Values for each field are -0.2 – 2.7. Field length (including sign): 6 characters. Significant digits: 4. Precision digits: 3.
   - Antigen Excess Factor — Upper antigen limit set to prevent reporting of results affected by antigen excess. Values are 0 – 10. Field length (including decimal): 7 characters. Precision after decimal point: 4 digits.

   IMPORTANT: Before changing the default Antigen Excess Factor, for your UDA, please review “3: Antigen Excess” on page 3-1.

b. Touch Save to save the parameters and return to the Edit Results Parameters screen.

- If 2 Point with Antigen Excess Rate Check is selected as the assay model type, the following dialog is displayed when you touch More Assay Parms.

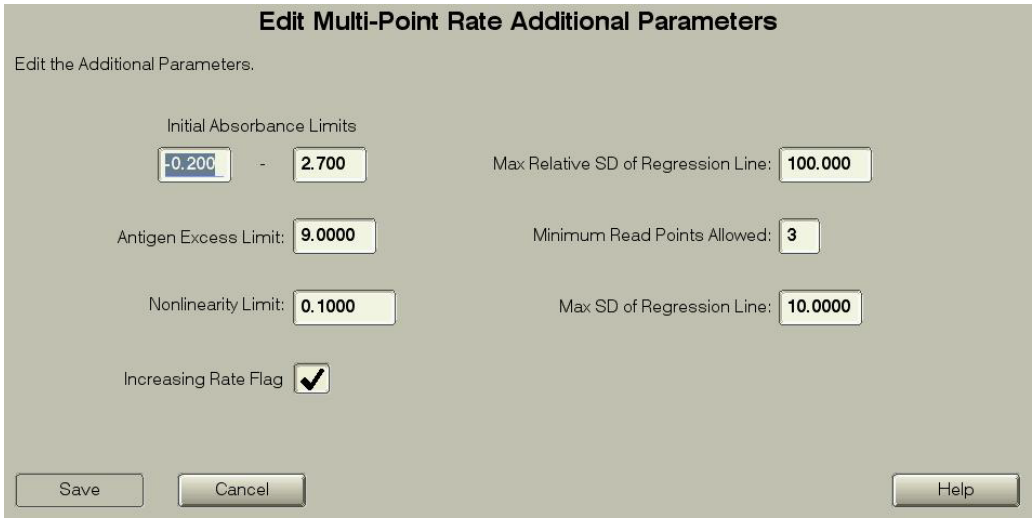


a. Edit the additional parameters for this assay.
   - Initial Absorbance Limits — Range of values expected at the assay's first read to determine whether it is within the expected assay range. Values for each field are -0.2 – 2.7. Field length (including sign): 6 characters. Significant digits: 4. Precision digits: 3.
   - Second Absorbance Limits — Range of values expected at the assay's second read to determine whether it is within the expected assay range. Values for each field are -0.2 – 2.7. Field length (including sign): 6 characters. Significant digits: 4. Precision digits: 3.
   - Antigen Excess Factor — Used to calculate upper antigen limit to prevent reporting of results affected by antigen excess. Values are 0 – 10. Field length (including decimal): 7 characters. Precision after decimal point: 4 digits.

     IMPORTANT: Before changing the default Antigen Excess Factor, for your UDA, please review "3: Antigen Excess" on page 3-1.
   - Early Rate Read Index — Indicates that the earliest-read value is not included in the response computation. Values are 1 or 2. Field length: 1 character. (Not displayed for 2-Point Rate assays without antigen excess rate check)

b. Touch Save to save the parameters and return to the Edit Results Parameters screen.

- If Multi Point is selected as the assay model type, the following dialog is displayed when you touch More Assay Parms.

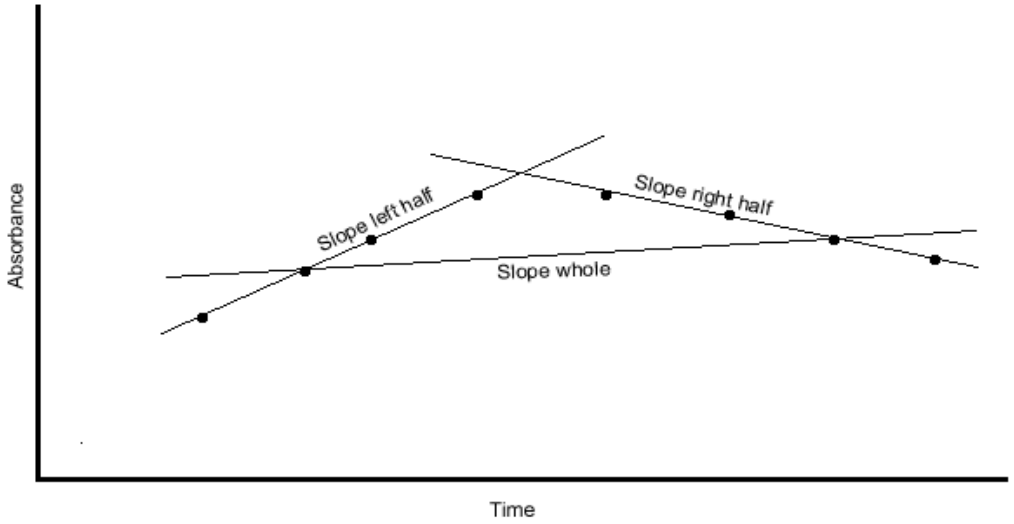


a. Edit the additional parameters for this assay.

- Initial Absorbance Limits — Range of values expected at the system's first check of the calibration curve to determine whether it is within the expected spline range. Values for each field are -0.2 – 2.7. Field length (including sign): 6 characters. Significant digits: 4. Precision digits: 3.
- Antigen Excess Limit — Used to calculate upper antigen limit to prevent reporting of results affected by antigen excess. Values are 0 – 10. Field length (including decimal): 7 characters. Precision after decimal point: 4 digits.

IMPORTANT: Before changing the default Antigen Excess Factor, for your UDA, please review “3: Antigen Excess” on page 3-1.

- Nonlinearity Limit — Amount of curvature allowed prior to trimming the kinetic curve. Values are 0 – 1000. Field length (including decimal): 9 characters. Precision after decimal point: 4 digits.



Linearity Factor = ((slope left half) - (slope right half)) / slope whole

NOTE: Slopes calculated by using least square regression.

If (Linearity Factor < Nonlinearity Limit) use all points in regression

Else use linear cut algorithm to trim from end

- Increasing Rate Flag - Indicates whether the assay has an increasing absorbance with time (checked) or a decreasing absorbance with time (unchecked).
- Max Relative SD of Regression Line — Maximum noise allowed in a regression that can be used for a prediction (relative error). Values are 0 – 100. Field length (including decimal): 7 characters. Precision after decimal point: 4 digits.
  ((Max Sy · x in absorbance units) / (absorbance range)).

  NOTE: This is the maximum SD of residuals (relative to the absorbance range) of absorbances around a regression line through the kinetic curve allowed before trimming noisy points. Increasing the number will decease the number of noisy points removed. Decreasing this number will cause more points to be trimmed. Default values are set at the maximum level and essentially turn-off spike detection.
- Minimum Read Points Allowed — Minimum number of points required in regression after trimming or spike noise reduction to allow a response to be generated. Values are 0 – 12. Field length: 2 characters.

NOTE: This is the minimum number of kinetic points remaining, after trimming, needed to compute a response. If there are fewer than the Min Read Points Allowed after trimming out noisy points the replicate is rejected.

- Max SD of Regression Line — Maximum noise allowed in a regression that can be used for a prediction (absolute error). Values are 0 – 10. Field length (including decimal): 7 characters. Precision after decimal point: 4 digits.
  ((Max Sy · x in absorbance units).

  NOTE: This is the maximum SD of residuals of absorbances around a regression line through the kinetic curve allowed before trimming noisy points. Increasing the number will decrease the number of noisy points removed. Decreasing this number will cause more points to be trimmed. Default values are set at the maximum level and essentially turn-off spike detection.

b. Touch Save to save the parameters and return to the Edit Results Parameters screen.

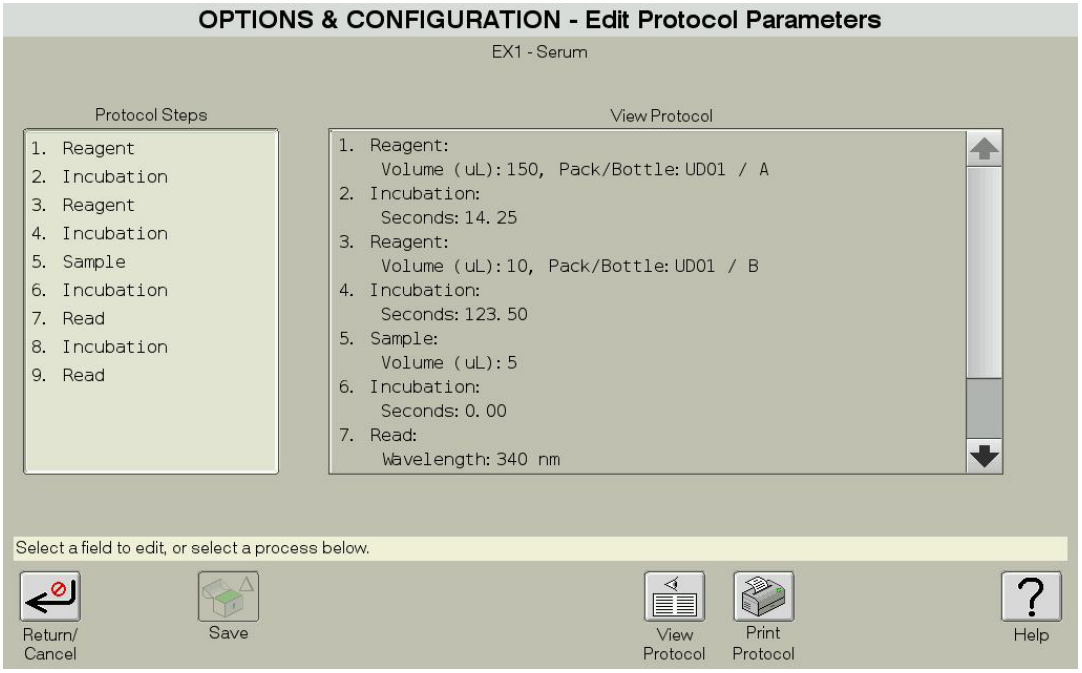
WARNING: ***Multi-point assay selection will decrease the throughput of all assays.***

Step 5: Configure Protocol Parameters

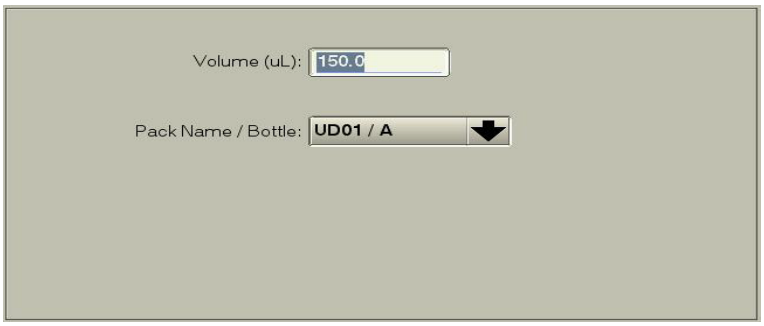
The protocol parameters that are configured in this step are dependent upon the template selected.

1. Touch Protocol Parms at the bottom of the Review/Edit Assay screen.
2. On the left side of the Edit Protocol Parameters screen, touch a protocol step (Reagent, Sample, Incubation, Read) in the list to select it. The right side of the screen displays the parameters for that step. The parameters that display depend on which type of protocol step you select. The steps that appear are determined by the template chosen.

   The screen is an example only, what you see will be dependent upon the template you selected.



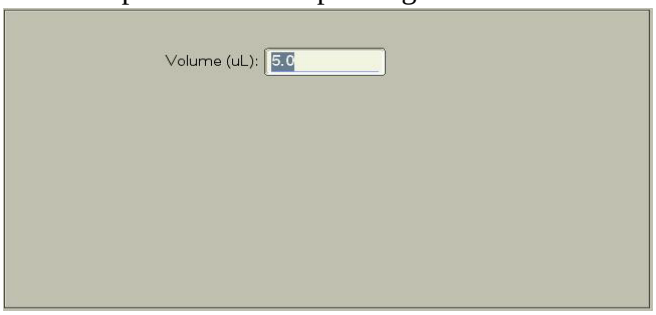
3. Touch a Reagent Protocol Step displayed on the left side of the screen to display the Reagent Protocol Step dialog.



   a. Type the volume (30 – 200µL in 0.1µL increments) of reagent in the text box. This volume is only applicable to the first reagent addition.

   b. Select a pack name/bottle designation from the pulldown menu.

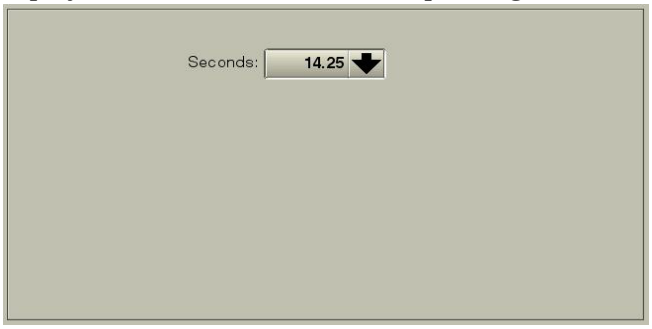
4. Touch a Sample Protocol Step displayed on the left side of the screen to display the Sample Protocol Step dialog.



   a. Type the volume of sample (2 – 59.9µL in 0.1µL increments) in the text box.

      NOTE: For samples that require pre-dilution (standard dilution), enter the volume of the diluted sample (sample plus diluent).

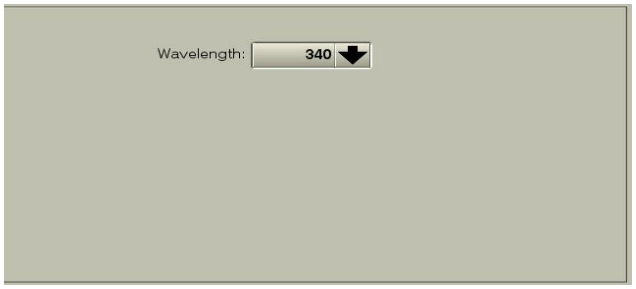
5. Touch an Incubation Protocol Step displayed on the left side of the screen to display the Incubation Protocol Step dialog.



   a. Select an incubation time from the pulldown menu.

      NOTE: If an Incubation Protocol Step is not needed, select 0 (zero) or the shortest available time displayed to work within the system timing cycle.

6. Touch a Read Protocol Step displayed on the left side of the screen to display the Read Protocol Step dialog.



   a. Select a wavelength from the pulldown menu or select “None” to disable the read protocol step.

      NOTE: The minimum total cuvette volume is 150µL. The maximum total cuvette volume is 250µL.

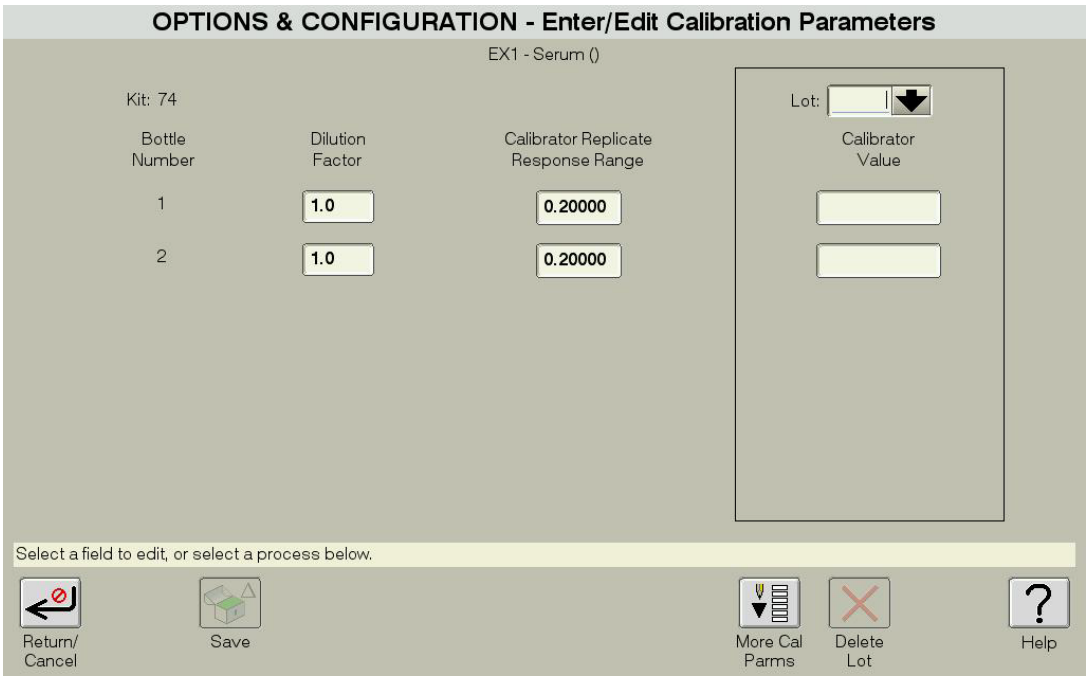
      NOTE: Disabled reads will be replaced by 9.5 seconds of incubation time.

7. When you finish configuring the protocol data, touch the Save button.
8. Touch the Print Protocol button to print the displayed protocol information.

Step 6: Configure Calibration Parameters

NOTE: If your UDA uses of a factor that is based on the molar extinction coefficient, please skip this step and Refer to “Molar Extinction Coefficient” in Appendix D of this UDA Reference Guide.

1. Touch Calibration Parms at the bottom of the Review/Edit Assay screen.



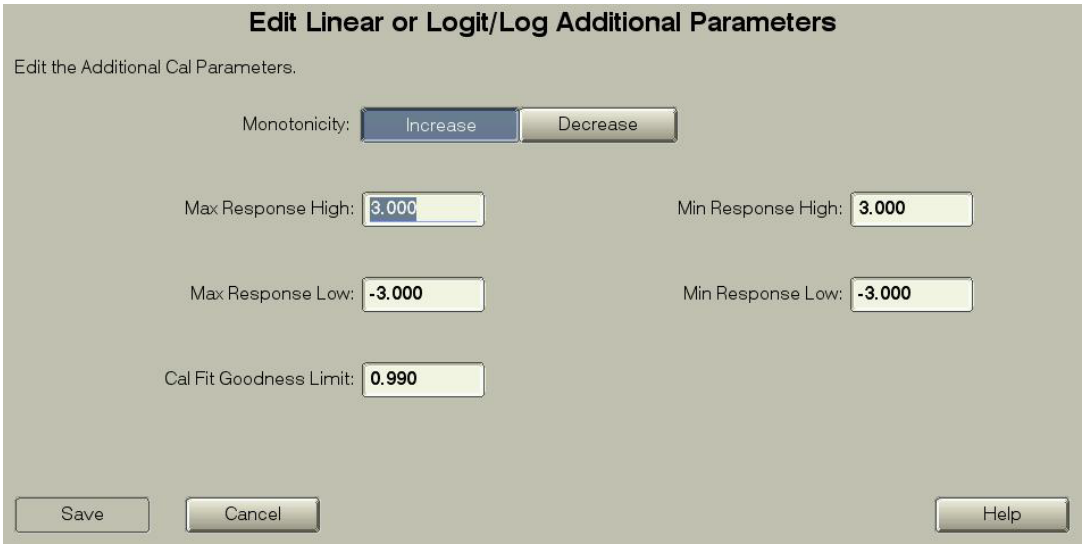
2. On the Edit Calibration Parameters screen, touch the Lot pulldown menu and select a calibrator lot number from the list or type a new lot number in the box (max. 2 digits).
3. Type calibrator values for each calibrator bottle for the lot you selected. The calibrator value is the known amount of analyte contained in the calibrator (1–5 characters including sign and decimal point, numeric).
4. Type new dilution factor values for each bottle if the calibrator requires dilutions prior to processing. The dilution factor is the automatic dilution factor for the assay to be calibrated (1 – 4 characters, including decimal point).

   NOTE: The limits on the factor are 1, 1.3-100 and no less than tenths.

5. Type new calibrator replicate response range values for each bottle. This range is the maximum allowable difference between replicates of the same calibrator. Values are 0 to 0.2.
6. Touch Save to save the calibration parameters.
7. Touch More Cal Parms to configure additional Calibration parameters for the assay.

   NOTE: The dialog that displays to configure additional calibration parameters depends on the selected assay's calibration model: Linear, Logit/Log, and Cubic Spline.

- If Linear or Logit/Log is selected as the cal model type, the following dialog is displayed when you touch More Cal Parms.



a. Edit the following parameters for this assay:
   - Monotonicity — Indicates whether the calibration uses increasing or decreasing monotonicity.
   - Max Response High — Maximum high calibration response. Values are -1000 to 1000.
   - Max Response Low — Maximum low calibration response. Values are -1000 to 1000.
   - Min Response High — Minimum high calibration response. Values are -1000 to 1000.
   - Min Response Low — Minimum low calibration response. Values are -1000 to 1000.

   NOTE: If the lowest response from a calibration is less than the Min Response Low or greater than the Min Response High, the calibration is rejected. If the highest response from a calibration is less than the Max Response Low or greater than the Max Response High, the calibration is rejected. You can widen the acceptance range for lowest response (by increasing difference between Min Response High and Min Response Low) to decrease the chance of rejecting a calibration. You can also widen the acceptance range for highest response (by increasing the difference between Max Response High and Max Response Low). At the start of optimization these values may be maxed out to response defaults of -3.0 to 3.0 OD and then tightened as you add response checks to the UDA calibration. The defaults make this check inoperative.

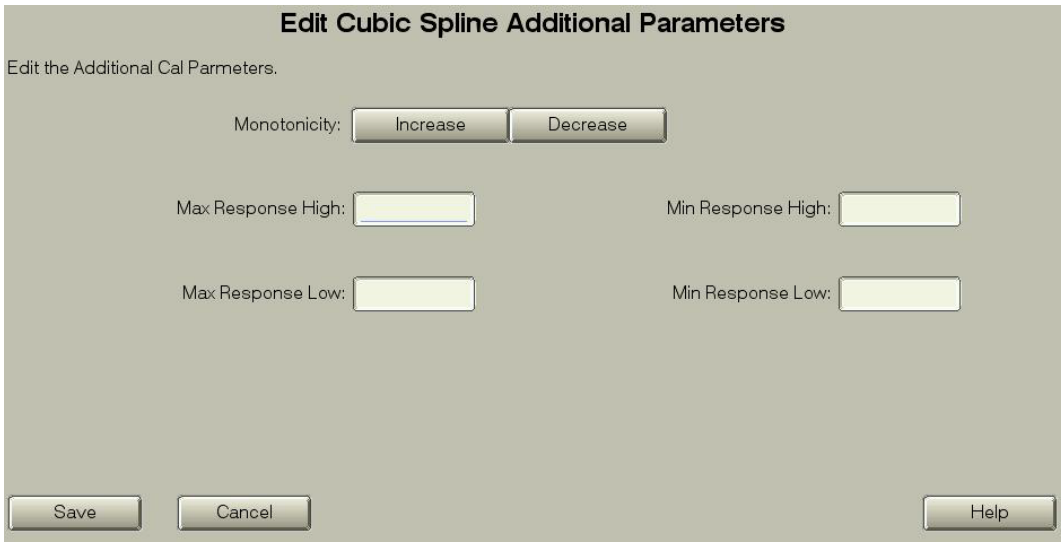
- Cal Fit Goodness Limit (R^2 Correlation Coefficient) — Measure of fit of the data points generated by the assay to the calibration model. Values are 0.000 to 1.000.

  NOTE: A value of 1.000 allows only a perfectly fit cal curve to be accepted. Anything smaller is less restrictive.

b. Touch Save to save the parameters and return to the Edit Results Parameters screen.

c. Touch Return/Cancel to continue and return to the Review/Edit Assay screen.

- If Cubic Spline is selected as the cal model type, the following dialog is displayed when you touch More Cal Parms.



a. Edit the following parameters for this assay:
   - Monotonicity - Indicates whether the calibration uses increasing or decreasing monotonicity.
   - Max Response High — Maximum high calibration response. Values are -1000 to 1000.
   - Max Response Low — Maximum low calibration response. Values are -1000 to 1000.
   - Min Response High — Minimum high calibration response. Values are -1000 to 1000.
   - Min Response Low — Minimum low calibration response. Values are -1000 to 1000.

   NOTE: If the lowest response from a calibration is less than the Min Response Low or greater than the Min Response High, the calibration is rejected. If the highest response from a calibration is less than the Max Response Low or greater than the Max Response High, the calibration is rejected. You can widen the acceptance range for lowest response (by increasing difference between Min Response High and Min Response Low) to decrease the chance of rejecting a calibration. You can also widen the acceptance range for highest response (by increasing the difference between Max Response High and Max Response Low). At the start of optimization these values may be maxed out to response defaults of -3.0 to 3.0 OD and then tightened as you add response checks to the UDA calibration. The defaults make this check inoperative.

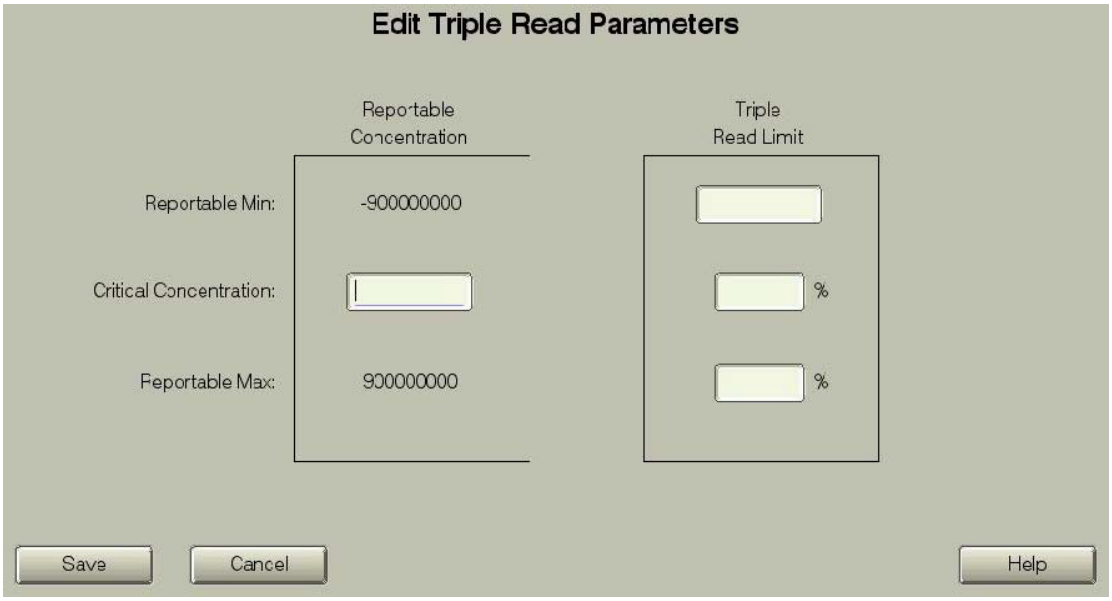
b. Touch Save to save the parameters and return to the Edit Results Parameters screen.

c. Touch Return/Cancel to continue and return to the Review/Edit Assay screen.

Step 7: Configure Triple Read Parameters

IMPORTANT: Before changing the default triple read parameters for your UDA, please review the triple read section of this UDA Reference Guide.

1. If changing triple read parameters is required, touch Triple Read Parms at the bottom of the Review/Edit Assay screen.



NOTE: The Reportable Min and Reportable Max are the reportable range of values you entered for this UDA on the Edit Result Parameters screen.

2. Type the Critical Concentration. The default is the mid point between and Reportable Min and Reportable Max.
3. Type the Triple Read Bias Limit for the Reportable Minimum value. If you change this value it must be greater than 0.
4. Type the Triple Read % Bias Limit for the Critical Concentration.
5. Type the Triple Read % Bias Limit for the Reportable Maximum.
6. Touch Save.

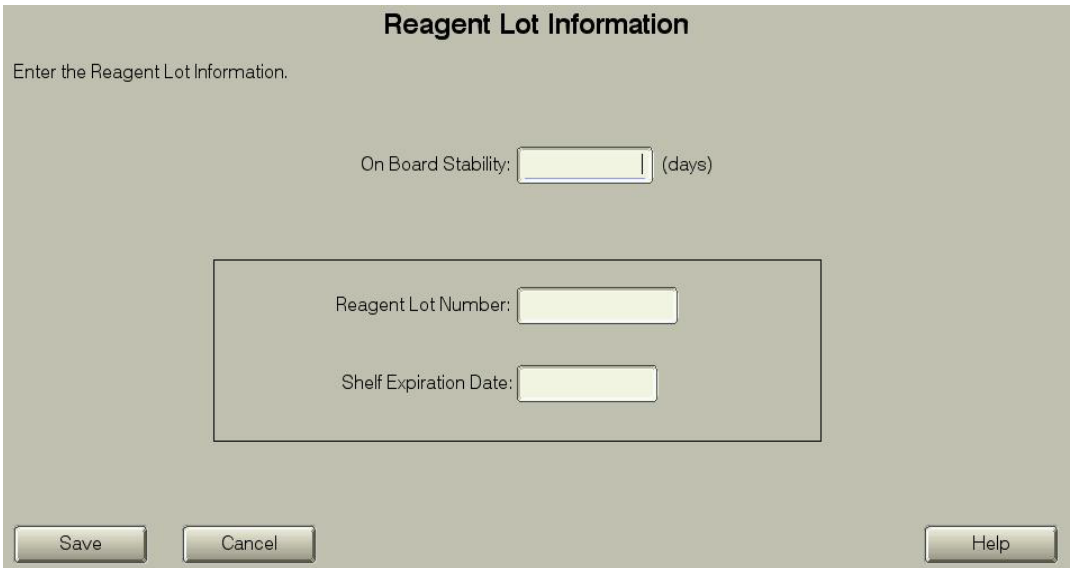
WARNING: ***Larger Triple Read Limits can degrade precision while a lower limit can improve precision but can suppress potentially good results. The goal is to set the appropriate balance between these two factors.***

Step 8: Enter Reagent Lot Information

Reagent Lot information is used to track the on board stability and shelf expiration for a reagent. This information can be accessed from any of the Review/Edit Assay screens by touching the Reagent Lot button at the bottom of the screen.

NOTE: The Reagent Lot Number is printed on the Calibration Report and is uploaded to the LIS if so configured as part of the extended result information. Both the lot number of the reagent pack and the user-defined Reagent Lot number from this screen are included on the Calibration Report.

1. Touch the Reagent Lot button.



2. Specify the On Board Stability, in days (1-99), for the reagent. Reagents that are on board for longer than the specified period are flagged on the Reagent Management screen and on the Results report.

   NOTE: Any change to the on board stability for an existing reagent is automatically calculated for any packs of that reagent currently on board.

   NOTE: The system does not track calibration interval stability.

3. Type the Reagent Lot Number, up to 12 characters.
4. Type the Shelf Expiration Date of the reagent. Expired reagents are flagged on the Reagent Management screen and on the Results report.

   NOTE: Any change to the shelf expiration date for an existing reagent is not reflected until a new pack of that reagent is loaded.

5. Touch Save.

NOTE: All reagent packs used by this assay are updated with this information.

WARNING: ***Tests have shown that some reagents have lower on board stability at lower residual volumes in the pack. Manufacturers' test data may not be applicable to the VITROS 5, 1.***

Step 9: Fill Reagent Packs

NOTE: Reagent Lot information must be entered before a reagent can be loaded onto the system.

IMPORTANT: Be sure to follow these instructions whenever you fill Ortho-Clinical Diagnostics reagent packs.

CAUTION: Do not use reagent packs that are damaged or that have any damaged packaging. Verify that labels and caps are secured. To avoid damage, be careful when opening the outer packaging with sharp instruments.

CAUTION: Use caution when considering reagents such as strong alkaline and acid solutions, organic solvents, viscous liquids, heavy metals, metal chelating agents, bleach, or ammonia. These materials may have adverse effects on the system and may produce incorrect results for both OCD-supplied and User Defined Assays.

IMPORTANT: Do not reuse reagent packs.

NOTE: Reagent is assigned to a reagent pack and bottle on the Edit Protocol Parameters screen when a Reagent Protocol Step is selected.

1. Inspect the packaging for any signs of damage. Remove the reagent pack from the carton and ensure that the pack is not damaged. The label and cap should be securely attached.
2. Write any necessary information about the reagent on the label before you fill the pack.
3. Estimate the fill volumes for the reagent packs, based on the ratio of Reagent A to Reagent B. Refer to Appendix A: for reagent volume ranges and dead volumes.

   NOTE: An optional tray (catalog # 6802120) is available to hold reagent packs while you fill them.
4. Remove the cap from Bottle A . Keep the cap on Bottle B.
5. Ensure that there are no particulates in the reagent, and then transfer the reagent into Bottle A gently to prevent foaming or splashing.
6. Replace the cap on Bottle A. Tighten the cap until it is snug enough to protect the reagent and provide sufficient resistance for the MICROTIP PACK OPENER.
7. If Bottle B is being used, remove the cap from Bottle B.
8. Repeat step 5. and step 6. for Bottle B, if a second reagent is used.

9. After you fill both bottles, store the pack according to reagent instructions until you are ready to load it onto the system.

   IMPORTANT: Do not loosen or remove the caps before you load the reagent pack.

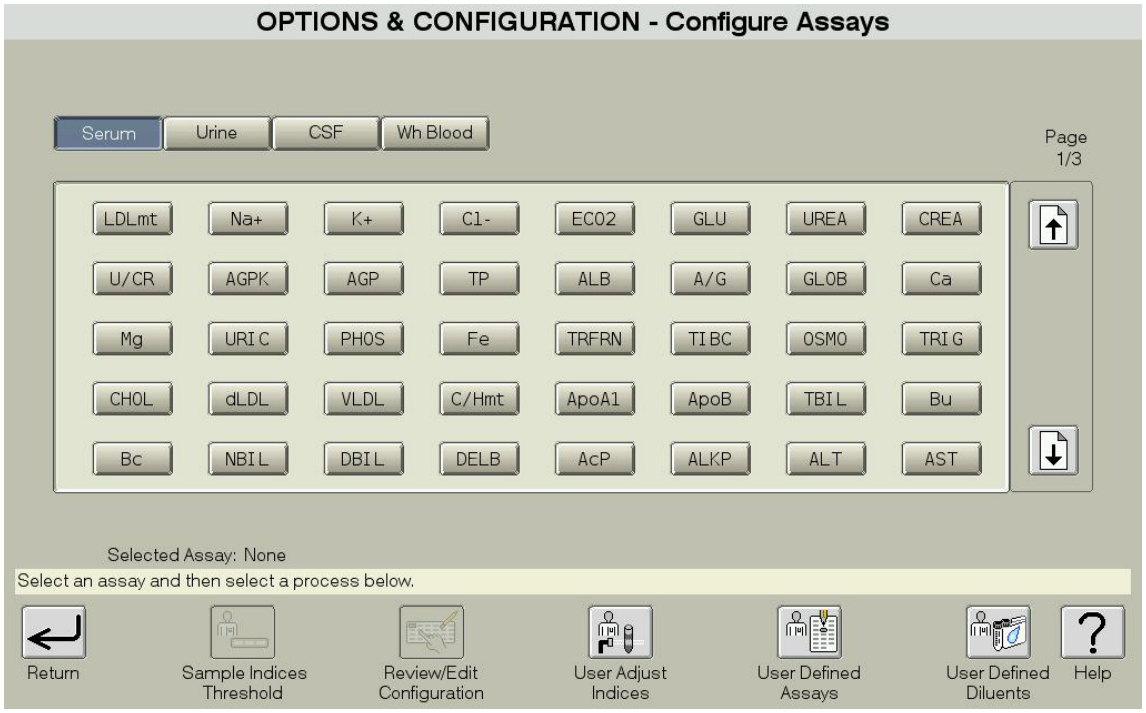
10. Load the reagent pack. Please refer to V-Docs for more information on loading a reagent pack.

WARNING: ***High fluid heights can trigger false bubble detection codes.***

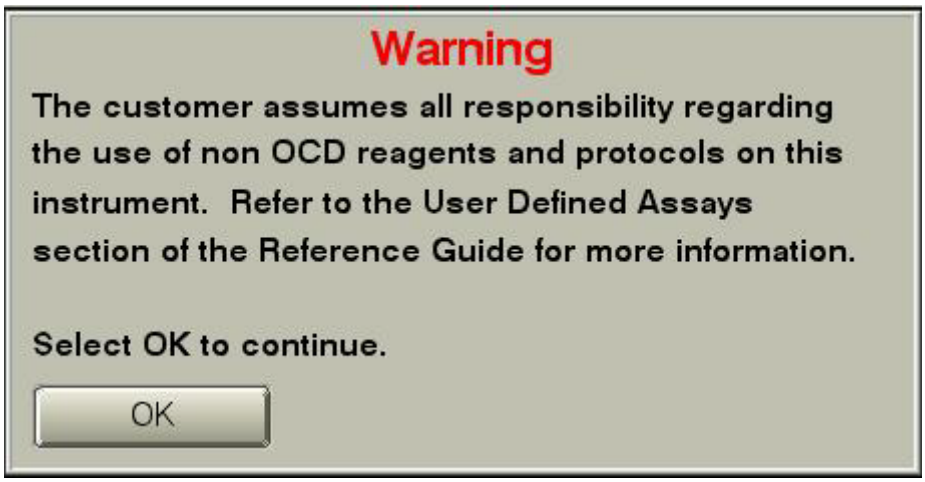
Maintaining UDAs

Reviewing a User Defined Assay

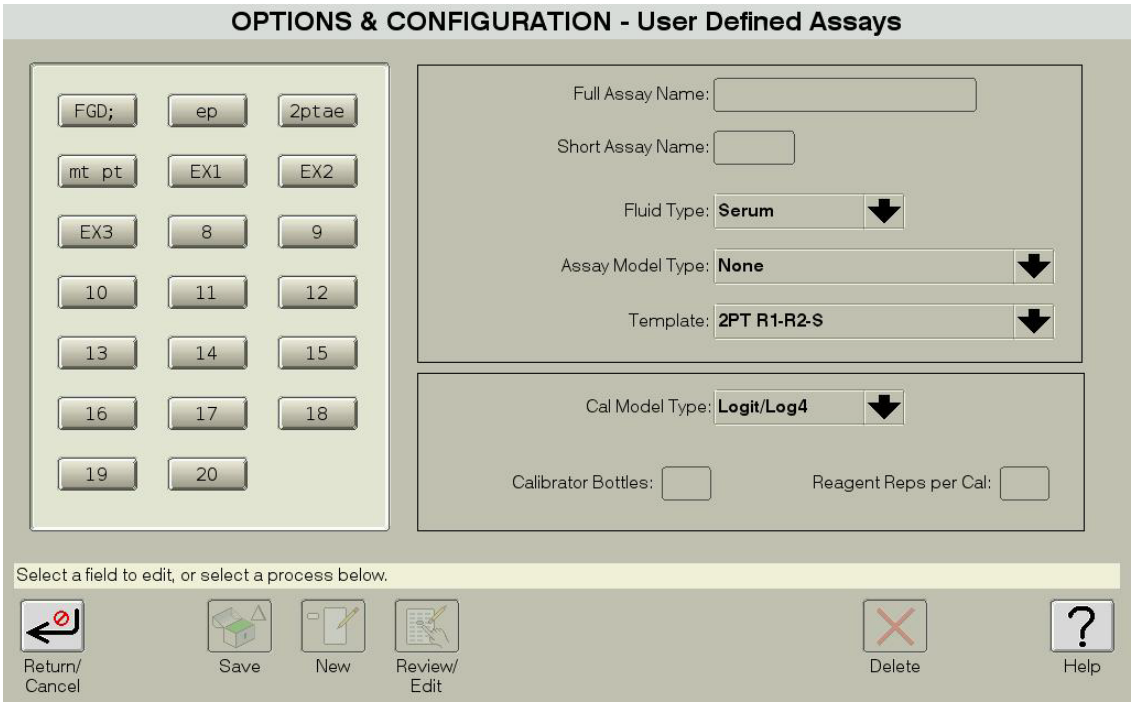
1. Touch Options.
2. On the Options and Configuration screen, touch Configure Assays.



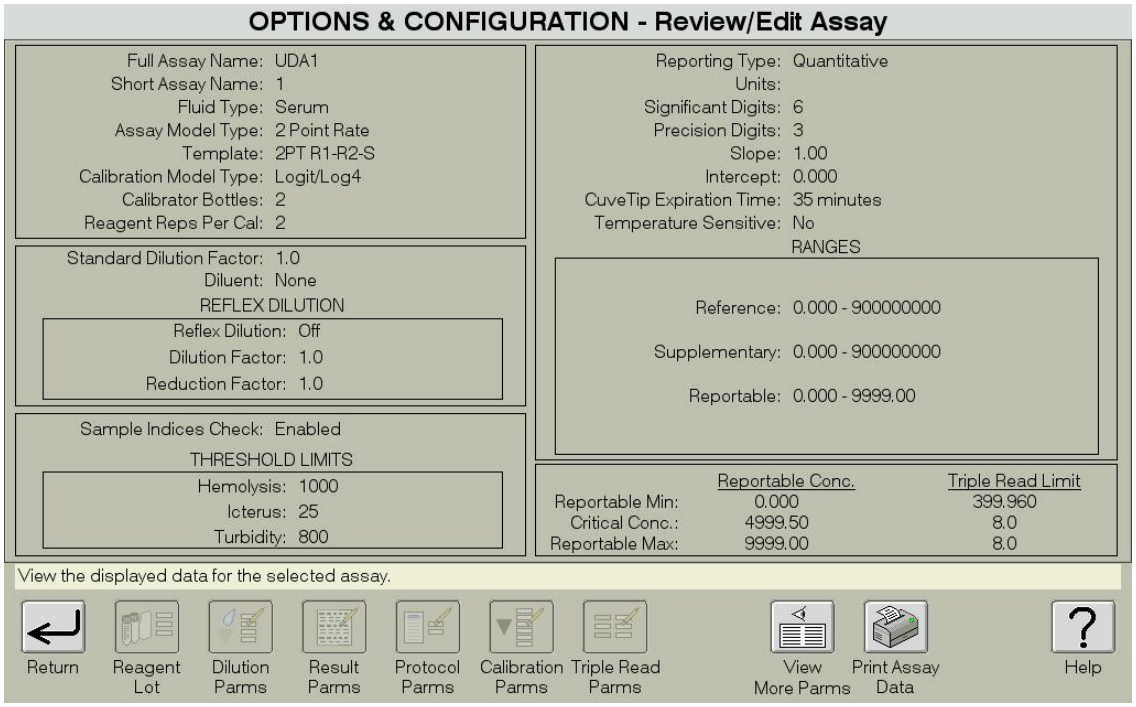
3. On the Configure Assays screen, touch the User Defined Assays button.
4. Touch OK to continue after reading and accepting the warning statement.



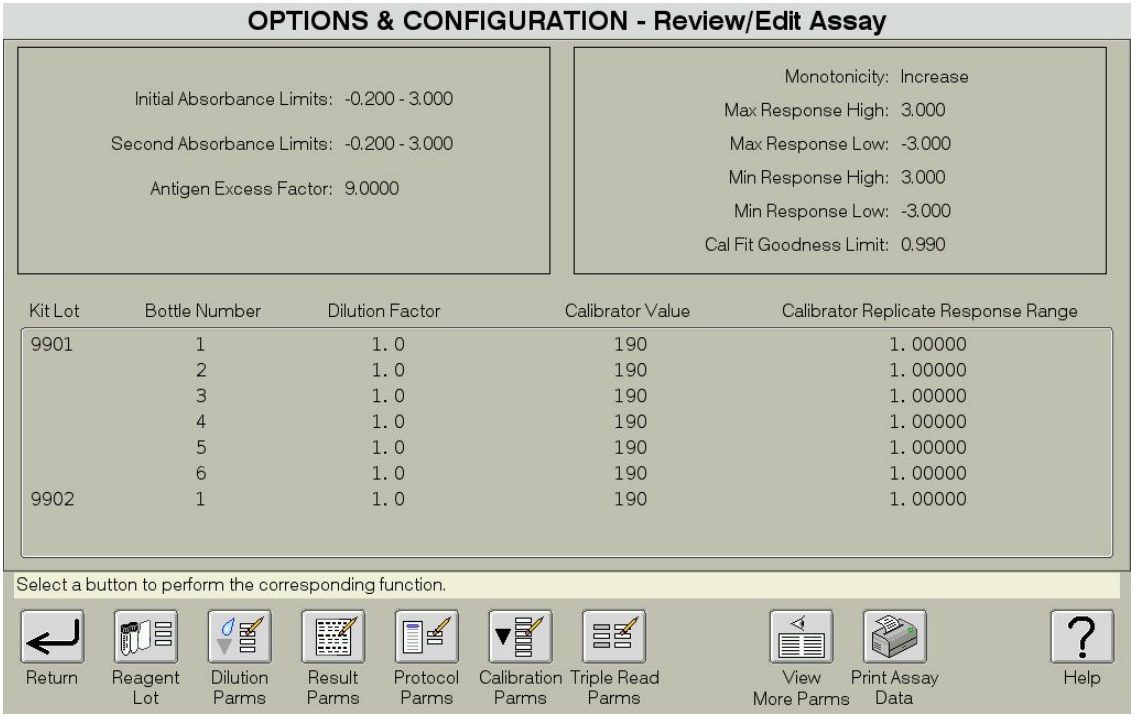
5. On the User Defined Assays screen, touch one of the 20 assay buttons to select the assay to review.



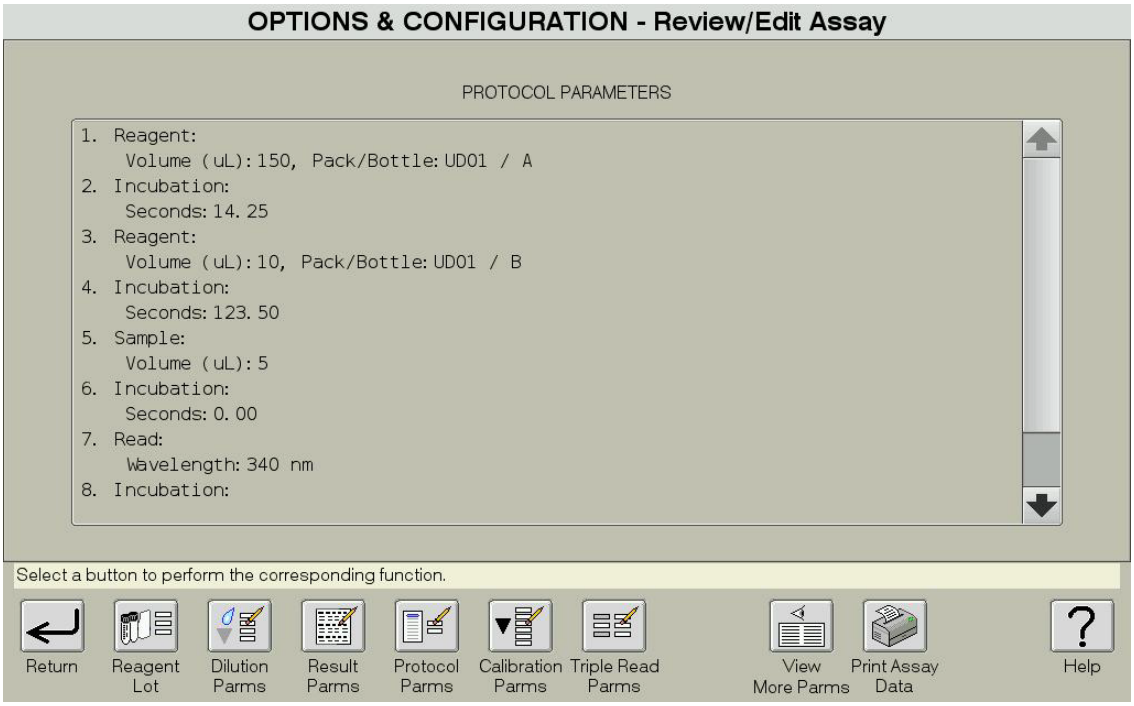
6. Touch the Review/Edit button. The first of three review/edit assay screens displays. These screens show the details of a UDA based on the calibration model type, assay model type, and template selected.



7. Touch View More Parms to move to the second review/edit assay screen.



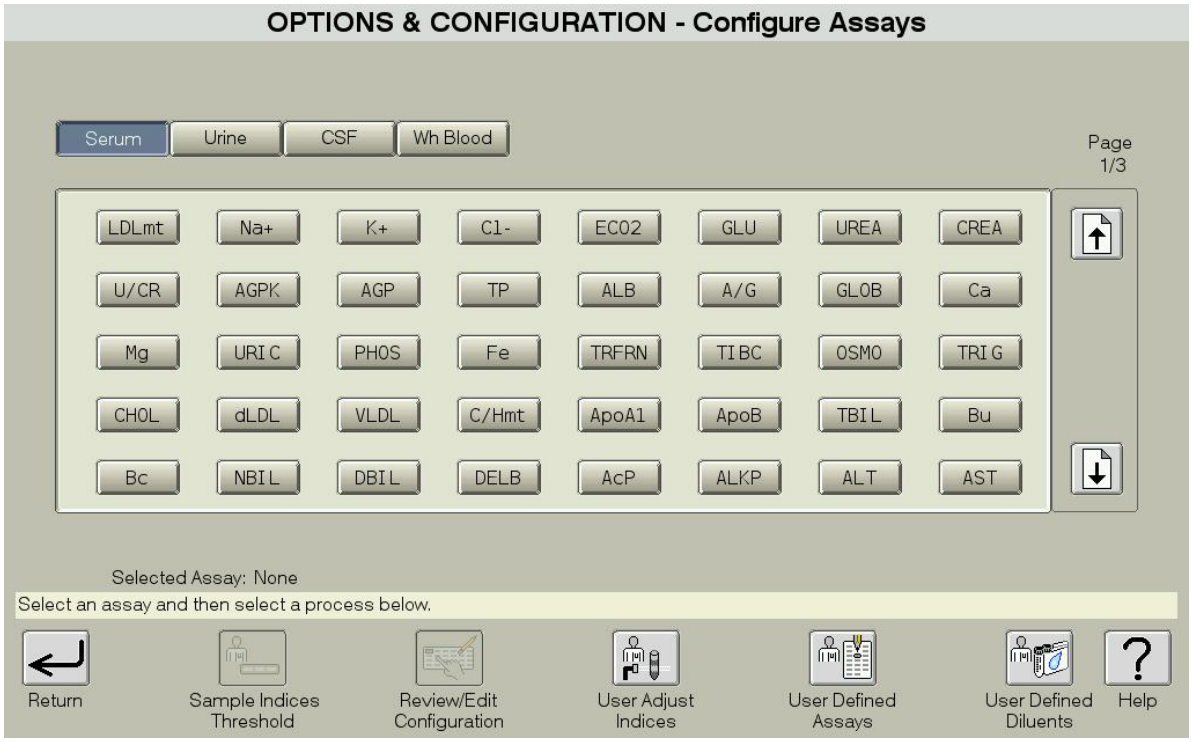
8. Touch View More Parms to display the third and final review/edit assay screen.



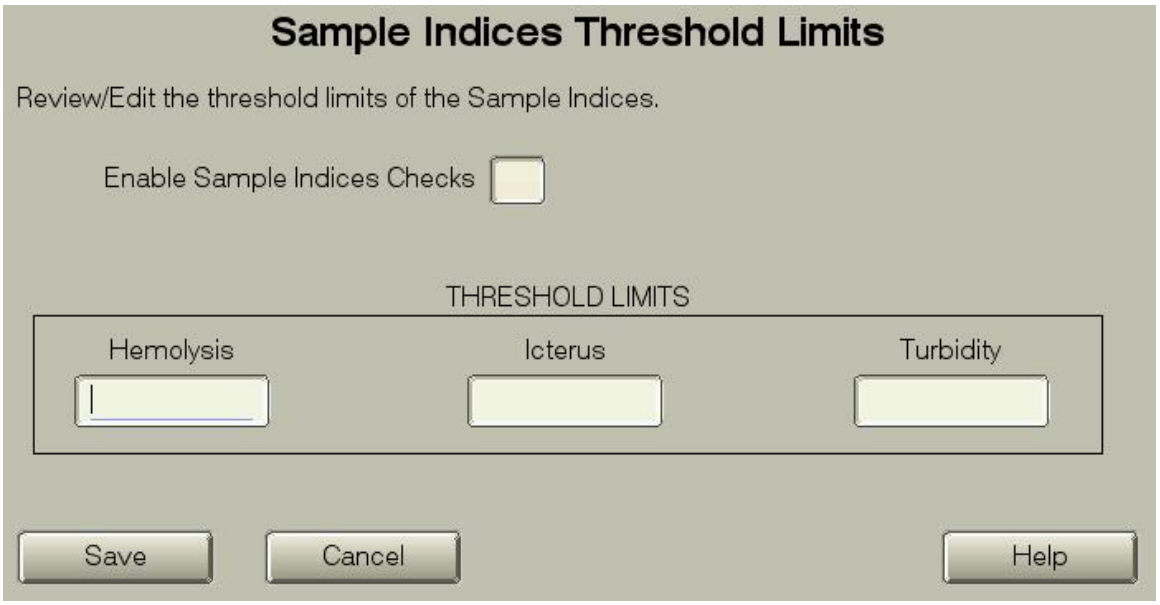
9. Touch View More Parms to cycle through the three review/edit assay screens.

Configuring Sample Indices Threshold Limits

1. Touch Options, and then touch Configure Assays.



2. On the Configure Assays screen, touch the appropriate Body Fluid button and Assay button for the assay you wish to configure limits for, and then touch Sample Indices Thresholds.



3. Touch the check box for Enable Sample Indices Checks to select it, if it is not already checked. Default indices are set at the high end of the concentration values for each index.

4. Type new threshold values for hemolysis, icterus, and turbidity in their text boxes. Values above this threshold are flagged with the appropriate indice flag.
5. Touch Save.

Editing Reagent Lot Information

Reagent Lot information is used to track the on board stability and shelf expiration for a reagent. This information can be accessed from any of the Review/Edit Assay screens by touching Reagent Lot at the bottom of the screen.

IMPORTANT: If more than one user defined assay uses the same reagent, a change to the reagent lot information here applies to all UDAs that contain that reagent.

NOTE: Only one reagent lot can be on the system at a time. If the reagent lot on board changes, the on board packs are marked unusable and should be removed from the system.

1. Access the UDA that contains the reagent that you would like to edit.
2. Touch Review/Edit on the bottom of the User Defined Assay screen.
3. From one of the Review/Edit Assay screens, touch Reagent Lot.
4. Modify the On Board Stability, in days (1-99), for the reagent. Reagents that are on board for longer than the specified period are flagged on the Reagent Management screen and on the Results report.

   NOTE: Any change to the on board stability for an existing reagent is automatically calculated for any instances of that reagent currently on board.

5. Modify the Reagent Lot Number, up to 12 characters.

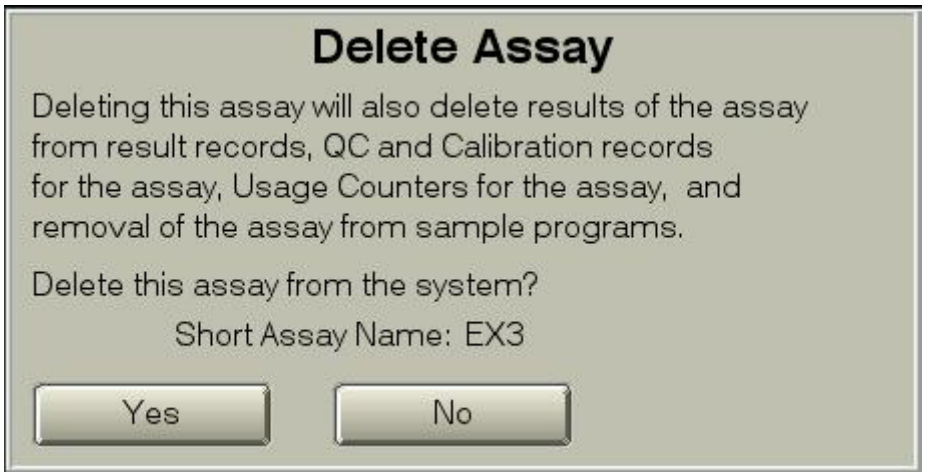
   NOTE: If you change the lot number, you should consider a recalibration of the UDA.

   NOTE: The user-defined Reagent Lot Number is printed on the Calibration Report and is uploaded to the LIS as part of the extended result information if so configured. Both the lot number of the reagent pack and the user-defined Reagent Lot number from this screen are included on the Calibration Report. When reviewing the Options, Review Calibration or Reagent Management screens, the Lot number displayed is the lot number assigned by OCD to the reagent pack.

6. Modify the Shelf Expiration Date of the reagent. Expired reagents are flagged on the Reagent Management screen and on the Results report.
7. Touch the Save button.

Deleting a User Defined Assay

1. On the User Defined Assays screen, touch one of the 20 assay buttons to select the assay.
2. Touch the Delete button.



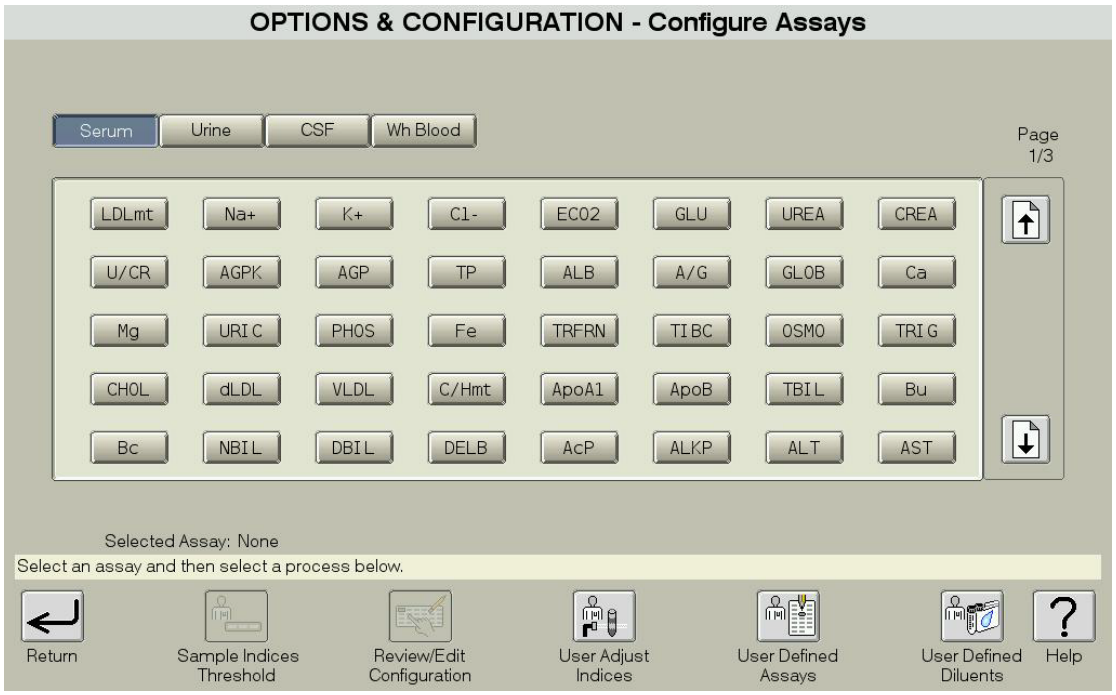
3. Touch Yes to delete the assay and its result records, QC and calibration records, and to remove the assay from sample programs.

Deleting a User Defined Calibrator Lot

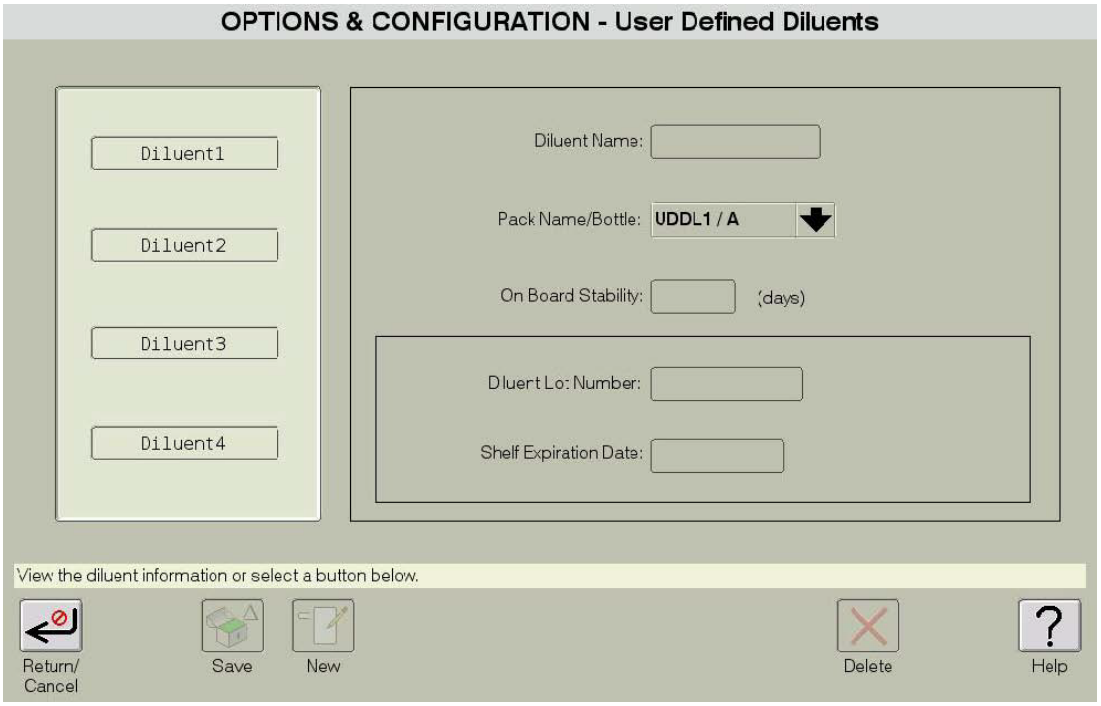
1. Touch the Calibration Parms button at the bottom of the Review/Edit Assay screen.
2. Select the lot to be deleted from the drop-down list.
3. Touch Delete Lot.
4. Touch Yes to delete the Calibration lot.

Defining a New User Defined Diluent

1. On the Options and Configuration screen, touch Configure Assays.



2. Touch User Defined Diluents at the bottom of the Configure Assays screen.



3. On the User Defined Diluents screen, touch New.
4. Type a name for the new diluent in the text box (max. 10 characters).

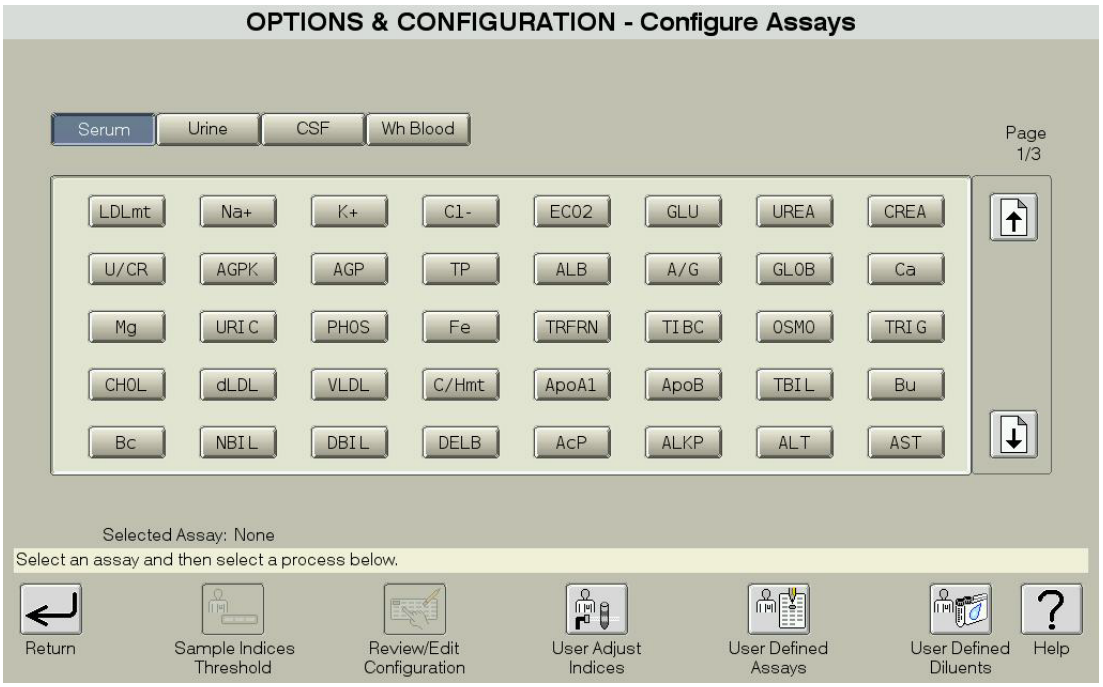
5. Select a pack and bottle designation for the new diluent from the pulldown menu.

   NOTE: Two bottles in each of the two diluent packs let you define up to four diluents. Bottle A is the inner chamber and Bottle B is the outer chamber.

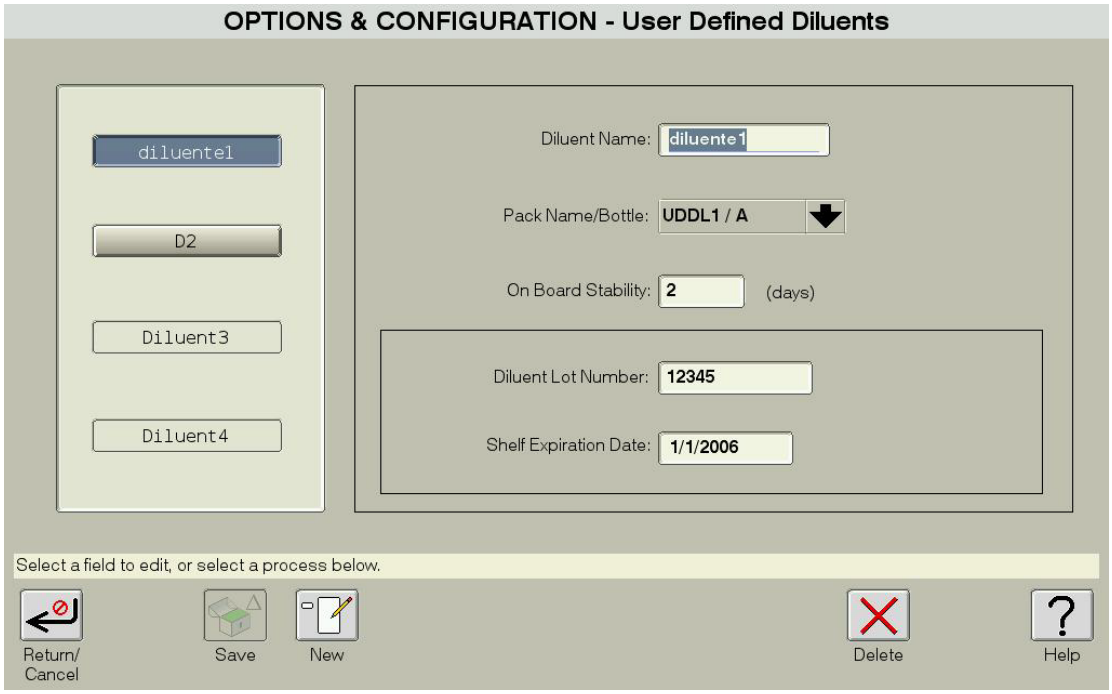
6. Specify the On Board Stability, in days, for the diluent.
7. Type the Diluent Lot Number, up to 12 characters.
8. Type the Shelf Expiration Date of the diluent.
9. Touch the Save button.

Deleting a User Defined Diluent

1. On the Options and Configuration screen, touch the Configure Assays button.



2. Touch the User Defined Diluents button at the bottom of the Configure Assays screen.



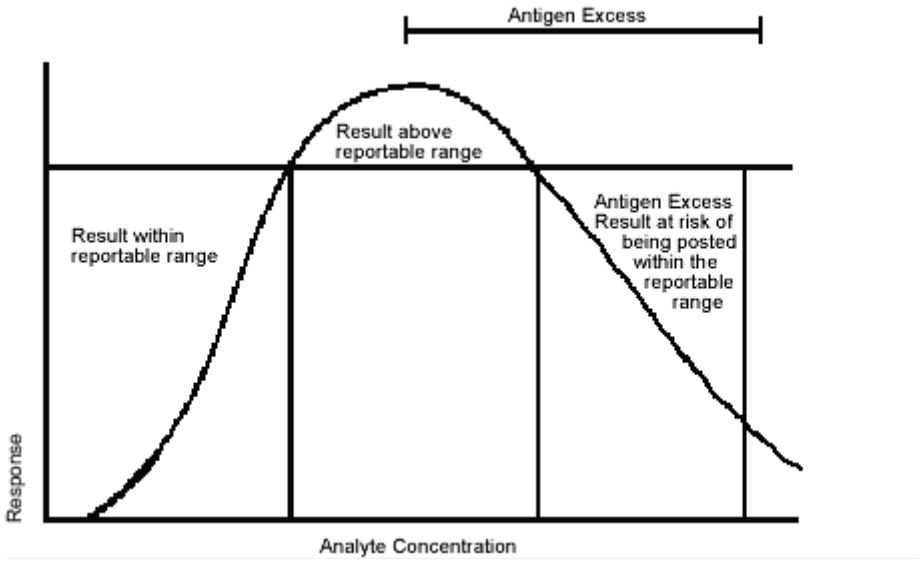
3. Select the Diluent that you would like to delete.
4. Touch the Delete button.
5. Touch Yes to delete the diluent.

3: Antigen Excess

Antigen Excess

IMPORTANT: If a UDA method has the potential to encounter an antigen excess condition, it is recommended that the user define an appropriate method for detection of this condition by the system. This section is intended to provide guidance regarding the programmable options available with the VITROS 5,1 FS Chemistry System for identification of an antigen excess condition. It is the user's responsibility to determine which option if any is best suited to a particular assay or method. For commercially available reagent kits other than those provided by OCD, the reagent manufacturer should provide guidelines and recommendations on how to detect antigen excess.

Antigen Excess refers to the region of the assay dose response curve where analyte (antigen) concentration exceeds the effective antibody concentration in the reaction, inhibiting the agglutination reaction.



The UDA feature allows you to configure an assay so that Antigen Excess is detected. The VITROS 5,1 FS system uses one of three methods to detect Antigen Excess:

1. **Early Absorbance Read** — The Antigen Excess flag is set at an absorbance level greater than the high calibrator absorbance when measured at the first read.

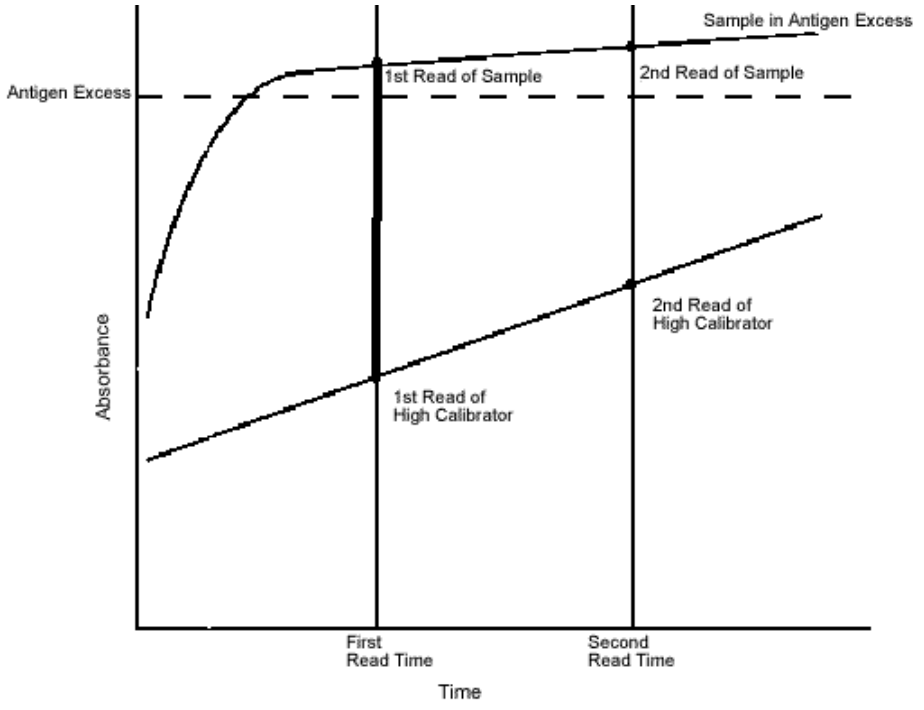
   NOTE: With the Early Absorbance Read method for Antigen Excess detection, highly turbid samples may trigger false Antigen Excess flags. In these cases, it is recommended to use the Early Rate Read method for Antigen Excess detection.

2. **Early Rate Read** — An additional absorbance reading is added to a 2-point rate assay, typically immediately after the last fluid addition step. This additional reading is used to take an early look at the reaction slope (change in optical absorbance per unit time) to determine if the observed slope is greater than a predetermined maximum slope limit.

3. **Slope Change** — This method is used with multi point kinetic assays only. For samples being tested for Antigen Excess, the reaction rate (change in optical absorbance per change in unit time) measured over the first 3 readings (rate C) is compared to the reaction rate measured over the last 3 readings (rate D) and a rate difference is calculated (see p. 9). When this rate difference exceeds a predetermined threshold, an antigen excess condition flag is posted.

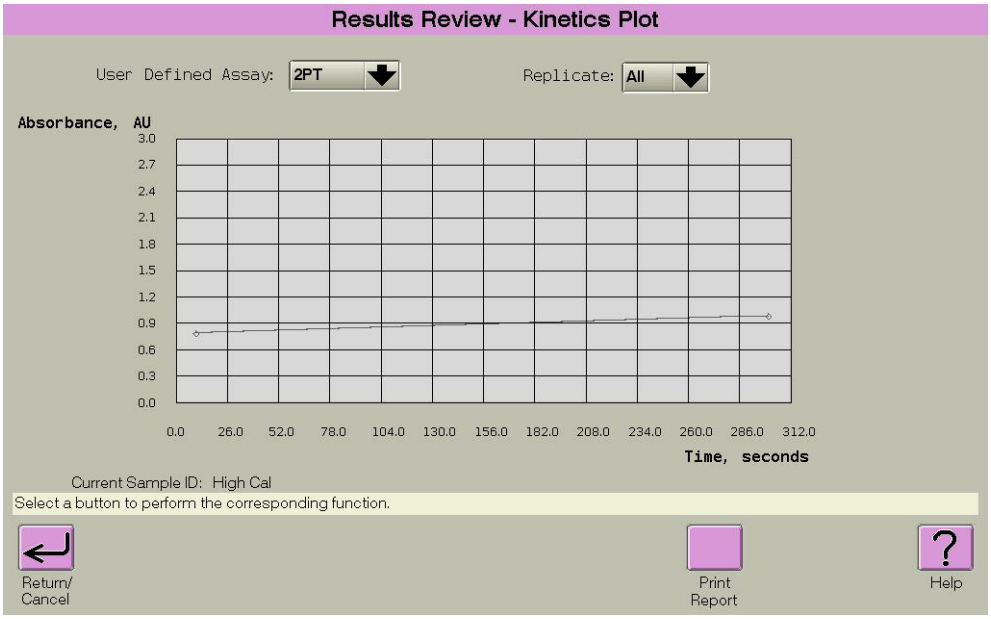
Method 1: Early Absorbance Read

The Antigen Excess flag is set at an absorbance level greater than the high calibrator absorbance when measured at the first read. The following graph illustrates this method of antigen excess detection.



The Antigen Excess flag using the early absorbance read is empirically determined and is set in the following manner:

1. Run the high calibrator as a sample.
2. Access the Kinetics Plot screen in Results Review.



3. Touch Print Report to view the absorbance value from the first read for the high calibrator.

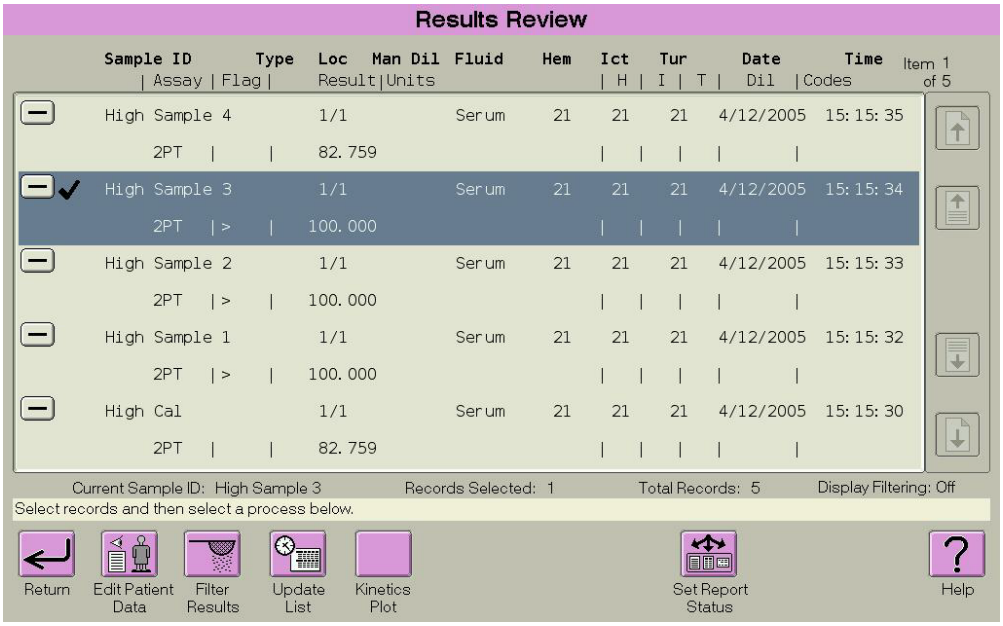
Kinetics Plot Data

Current Sample ID: High Cal
User Defined Assay: 2PT

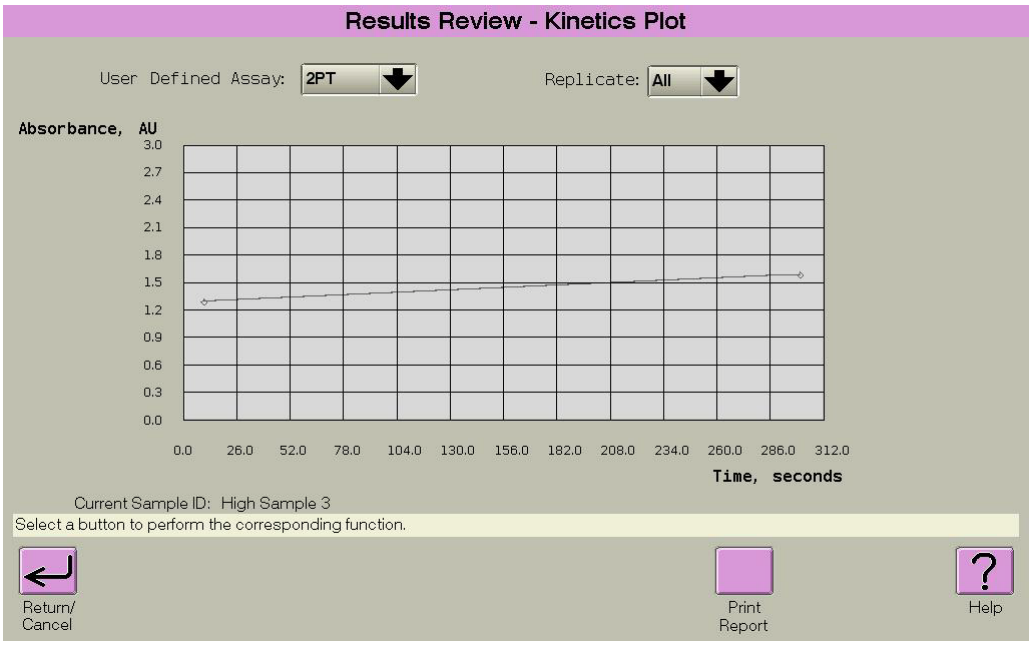
Replicate:	Time, seconds:	Absorbance, AU:	Response:
1	10.00	0.80	0.041379
1	300.00	1.00	0.041379

4. Make up a series of samples that are elevated and likely to give Antigen Excess.
5. Run the samples in order of increasing concentration.

6. Use the Results Review screen to view sample information. The last sample that is outside the reportable range should be viewed on the Kinetics Plot screen.



7. Access the Kinetics Plot screen in Results Review.



8. Touch Print Report to view the last sample that is outside of the reportable range on the Kinetics Plot screen to obtain the absorbance of its first read.

Kinetics Plot Data

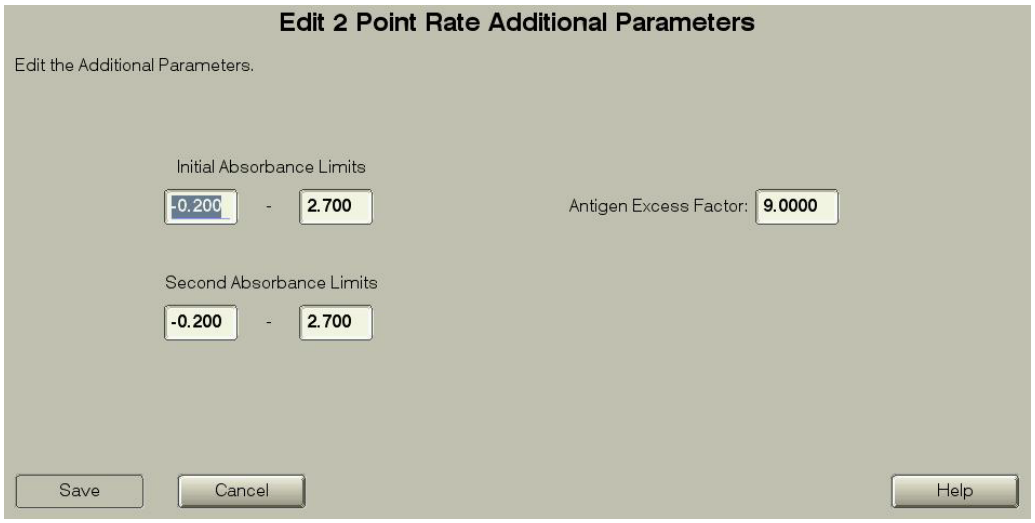
Current Sample ID: High Sample 3
User Defined Assay: 2PT

Replicate:	Time, seconds:	Absorbance, AU:	Response:
1	10.00	1.30	0.062069
1	300.00	1.60	0.062069

9. Obtain the Antigen Excess Factor by subtracting the absorbance of the high calibrator from the absorbance of the sample identified in step 6.

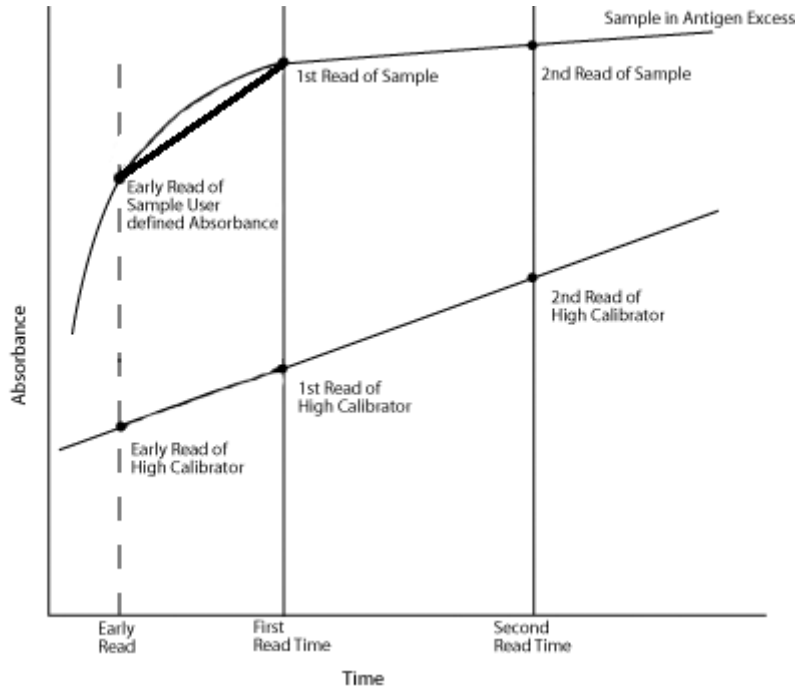
   For example if the absorbance of the first read of the high calibrator is 0.80 and the absorbance of the first read of the selected sample (determined in step 6. above) is 1.30, the Antigen Excess Factor is 0.50.

10. Enter the Antigen Excess Factor on the Edit 2 Point Rate Additional Parameters screen.



Method 2: Early Rate Read

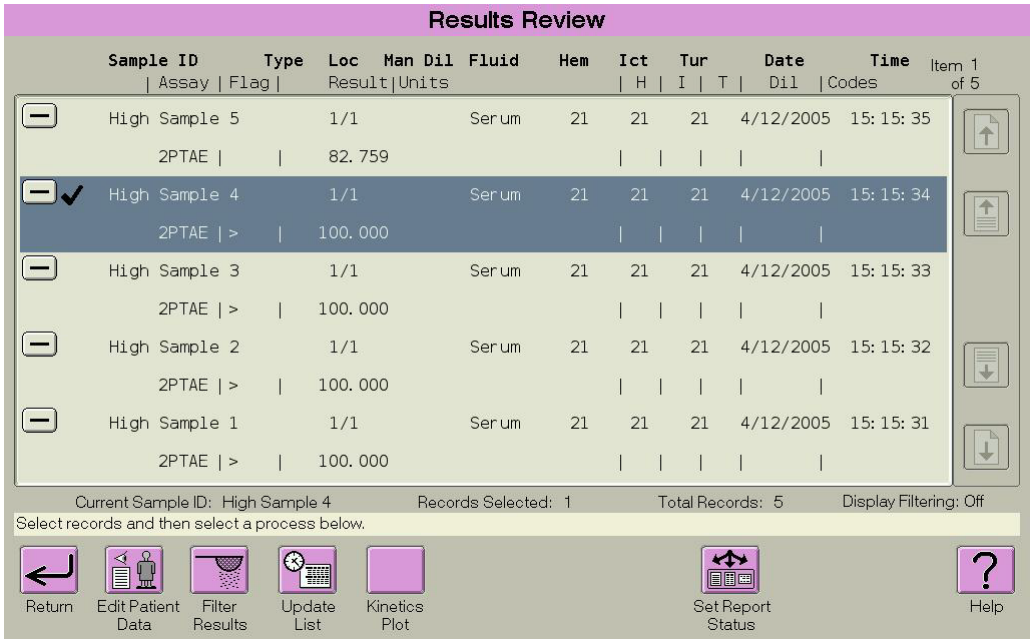
The early rate read method of determining Antigen Excess is preferred for samples with high turbidity because fewer false Antigen Excess flags are returned than in Method 1. The following graph illustrates this method.



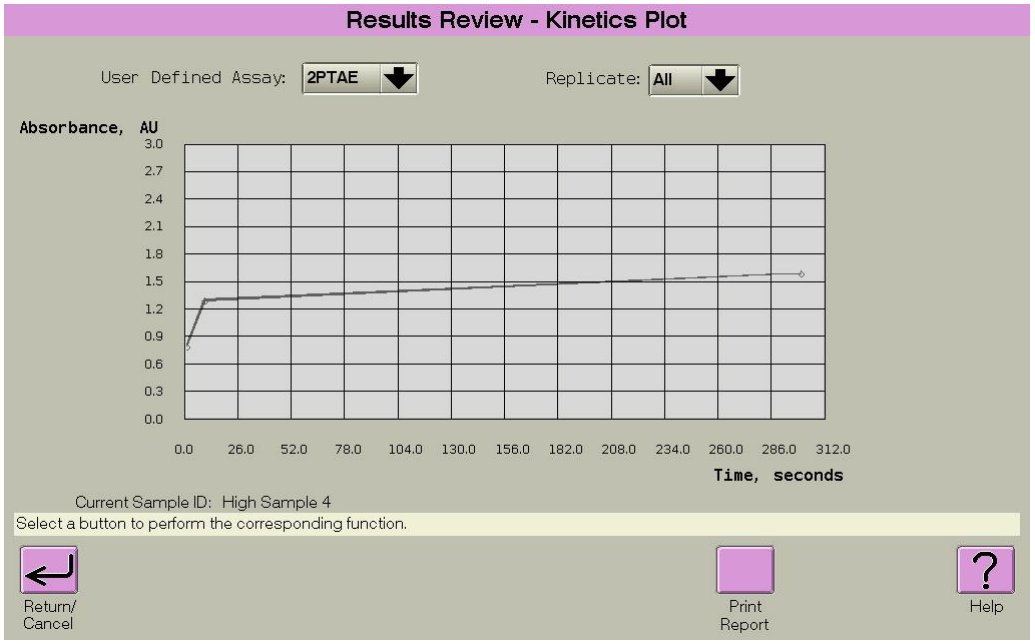
Set the Early Rate Read method using the following procedure:

1. Make up a series of samples that are elevated and likely to give Antigen Excess.
2. Run the samples in order of increasing concentration.

3. Use the Results Review screen to view sample information. The last sample that is outside of the reportable range should be viewed on the Kinetics Plot screen.



4. Access the Kinetics Plot screen in Results Review.



5. Touch Print Report to view the absorbance and time of the early and first reads for the sample identified in step 3.

Kinetics Plot Data

Current Sample ID: High Sample 4
User Defined Assay: 2PTAE

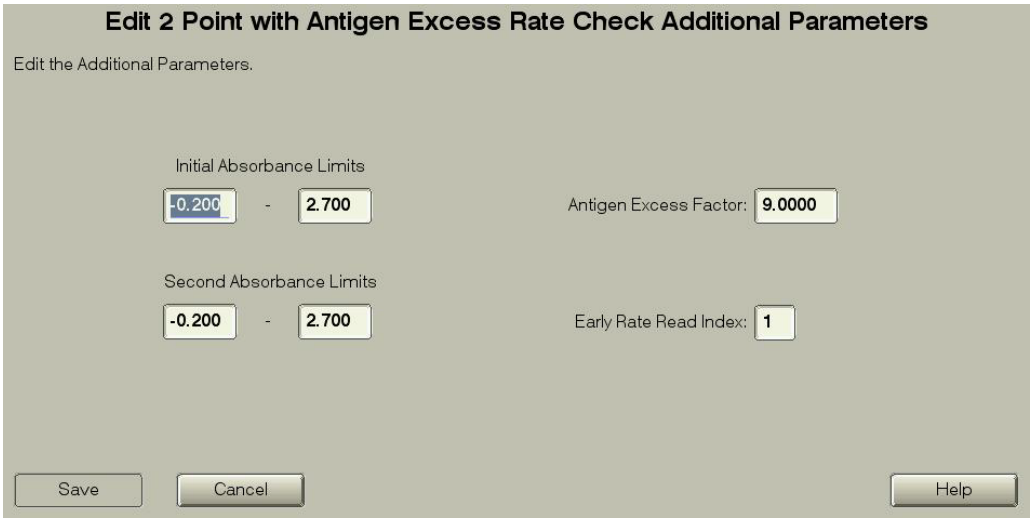
Replicate:	Time, seconds:	Absorbance, AU:	Response:
1	1.00	0.80	0.062069
1	10.00	1.30	0.062069
1	300.00	1.60	0.062069

A slope is determined using the early read and the first read:

(Δ absorbance / Δ time in minutes = slope)

For example, if the read for the early read taken at 1 second had an absorbance of 0.80 and the first read taken at 10 seconds had an absorbance of 1.30, the Antigen Excess Factor is 3.333.

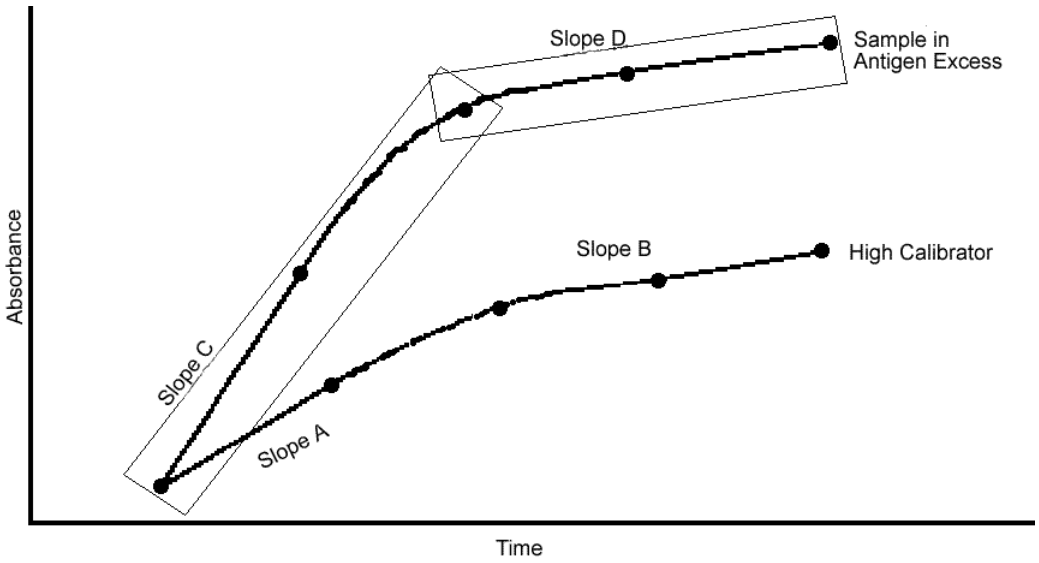
(Slope = 1.30 - 0.8 / 0.15 minutes = 3.333)



6. Enter the slope in the Antigen Excess Factor field in the Edit 2 Point with Antigen Excess Rate Check Additional Parameters screen.
7. The Early Rate Read Index field allows the operator to select which read is excluded from the final response in the Antigen Excess rate check.
   - Entering the number 1 instructs the software to not use the early read information when determining analyte concentration (the first and second read will be used).
   - Similarly entering a 2 eliminates the first read in calculations for analyte predictions (early and second reads are used in the two-point rate equation).

Method 3: Antigen Excess Defined Kinetics Slope Changes

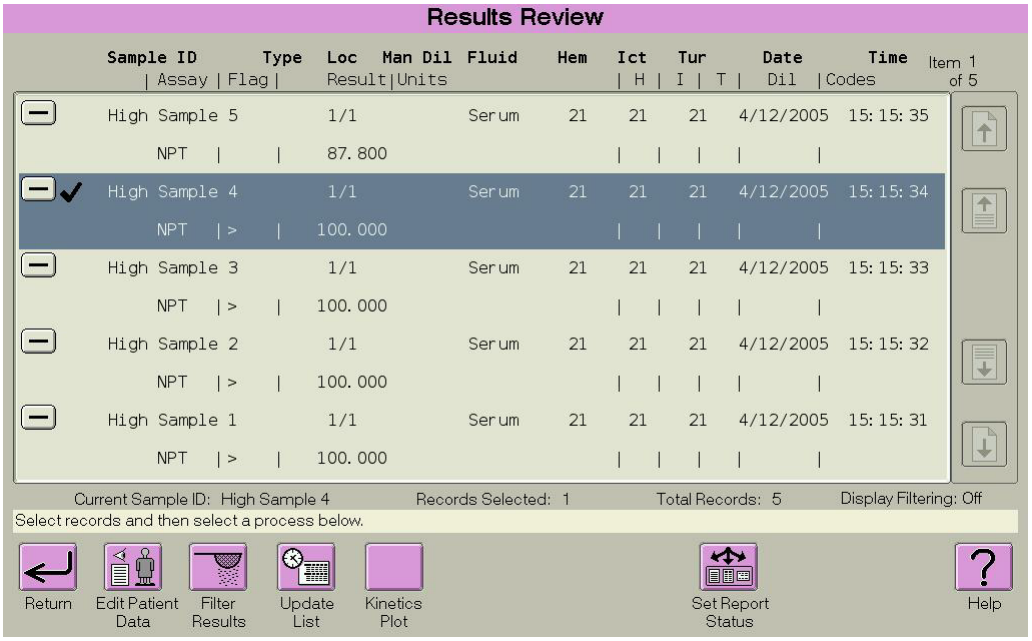
Multi point rate assays must use this method to detect Antigen Excess. This method can only be used for assays with 4 or more read points. The following graph illustrates this method. If the Slope C minus Slope D difference for an unknown sample exceeds the Antigen Excess limit a condition code is posted. The calibrator level 3 is provided for reference only and does not enter into the calculation for excess antigen.



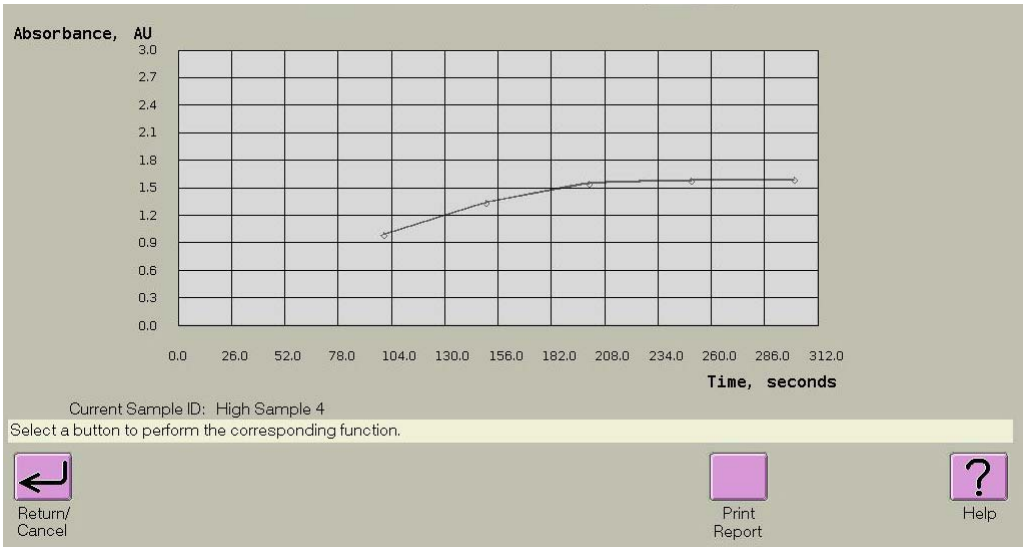
The Antigen Excess flag using kinetics slope changes is empirically determined and is set in the following manner.

1. Make up a series of samples that are elevated and are likely to give Antigen Excess.
2. Run the samples in order of increasing concentration.

3. Use the Results Review screen to view sample information. The last sample that is outside of the reportable range should be viewed on the Kinetics Plot screen.



4. Access the Kinetics Plot screen in Results Review.



5. Touch Print Report to view the absorbance and time all of the reads for the sample identified in step 3 using the Kinetics Plot screen in Results Review.
   - Calculate (using least squares regression) the slope for the first three points
   - Calculate the slope for the last three points

   NOTE: This method applies to assays with 4 to 12 reads. Assays with 4 or 5 reads will share points when making slope calculations. A three point kinetic will effectively disable the check.

Kinetics Plot Data

Current Sample ID: High Sample 4
User Defined Assay: NPT

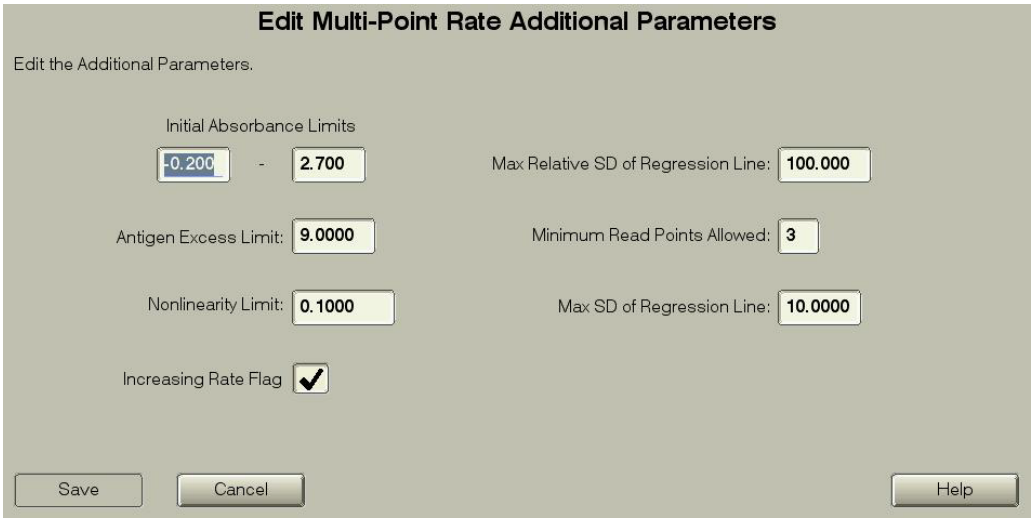
Replicate:	Time, seconds:	Absorbance, AU:	Response:
1	100.00	1.00	0.172800
1	150.00	1.35	0.172800
1	200.00	1.55	0.172800
1	250.00	1.59	0.172800
1	300.00	1.60	0.172800

In the example, the slope of the first three points is 0.33 and the slope of the last three points is 0.03.

6. Calculate the absolute value of the difference of the slope of the first three read points and the slope of the last three read points to detect a drop of the kinetic activity indicating Antigen Excess conditions.

   The Antigen Excess Limit from the example would be the absolute difference of 0.33 and 0.03, or 0.30.

7. This value is entered on the Edit Multi Point Additional Parameters screen as the Antigen Excess Limit.



The additional fields on this screen are not related to Antigen Excess. Please refer to the help text for this screen for more information about these fields.

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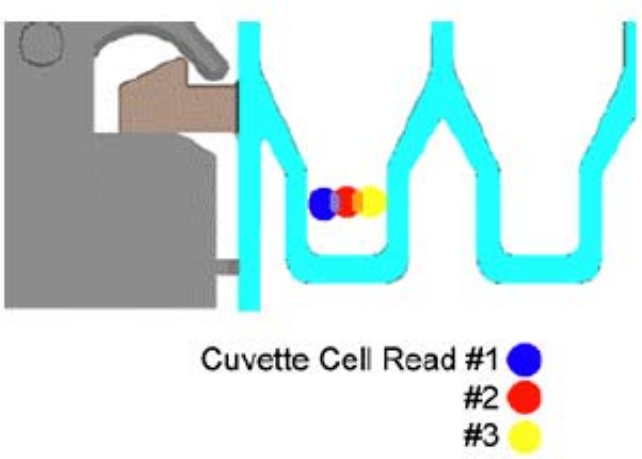
4: Triple Read Algorithm

Triple Read Algorithm

Triple reads are performed for each MicroTip cuvette to detect imperfections (air bubbles, atypical aggregates in liquids, etc.) that can affect concentration prediction. For each cuvette, the system performs optical reads at three different locations as illustrated below. A response is calculated at each location. The maximum difference among the three responses should be smaller than the triple read bias limit.



In a User Defined Assay, you can define bias limits in concentration on an assay by assay basis to detect imperfections in the optical path balanced against inappropriately rejecting an acceptable result. The bias limit can be based on either clinical need or analytical capability.

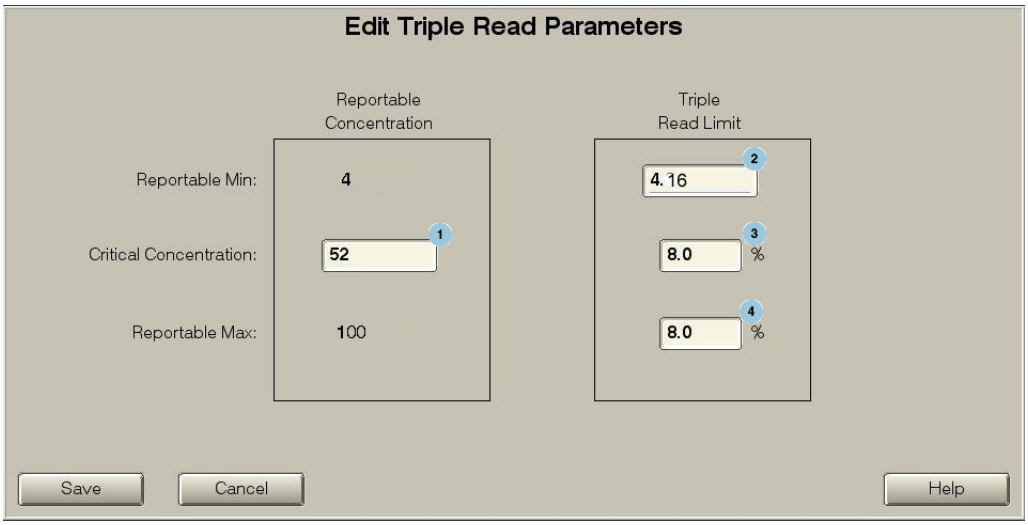
Triple Read Parameter Defaults

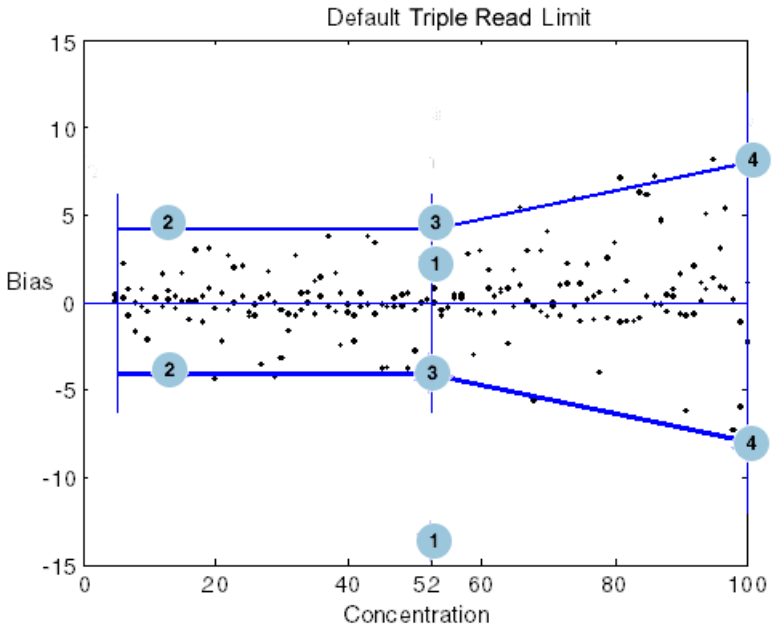
The default critical concentration is the midpoint of the reportable range.

Fom the reportable minimum to the critical concentration, the default triple read limit is 8% of the critical concentration (constant bias domain).

From critical concentration to reportable maximum, the default triple read limit is 8% of the concentration (constant % bias, variable bias domain).

This default triple read limit is illustrated in the following figures:





1	Critical Value = (Max - Min/2) + Min = (100 - 4)/2 + 4 = 52
2	Bias at Min Value = [Critical] · 0.08 = 4.16
3	Bias at Critical Value = [Critical] · (8/100) = 4.16
4	Bias at Max Value = [Max] · (8/100) = 8.00

Adjusting Triple Read Parameters

You can change the default triple read limits and the critical concentration when necessary. Tightening the triple read limits may cause more results to be surpressed. If you experience a large number of condition codes (U91-274) during assay optimization, the limits can be relaxed. This returns more results for review.

The following table is provided for the user to define the limits for triple read.

Reportable Concentration	Triple Read Limit
Reportable Minimum*	Real Number (>0.0)
Critical Concentration (CO)	% of C0
Reportable Maximum*	% of Cmax

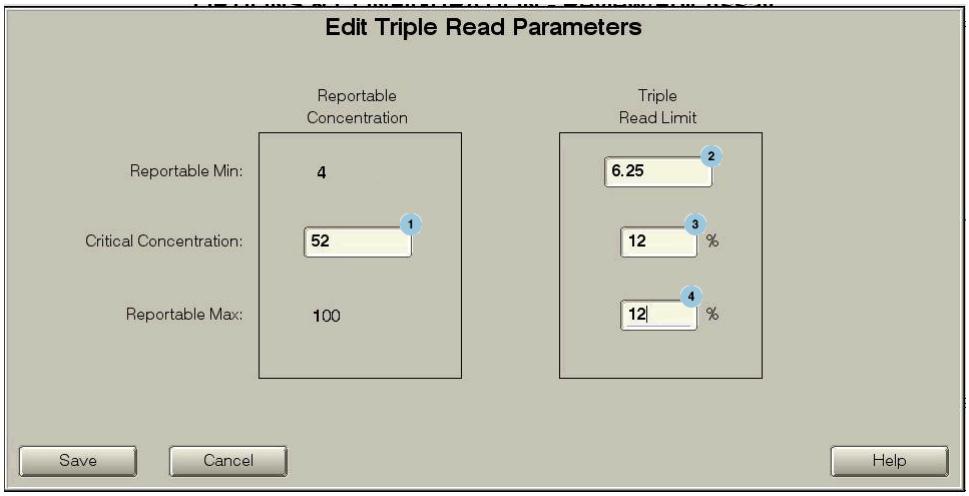
* The reportable minimum and maximum can only be adjusted on the Edit Result Parameters screen.

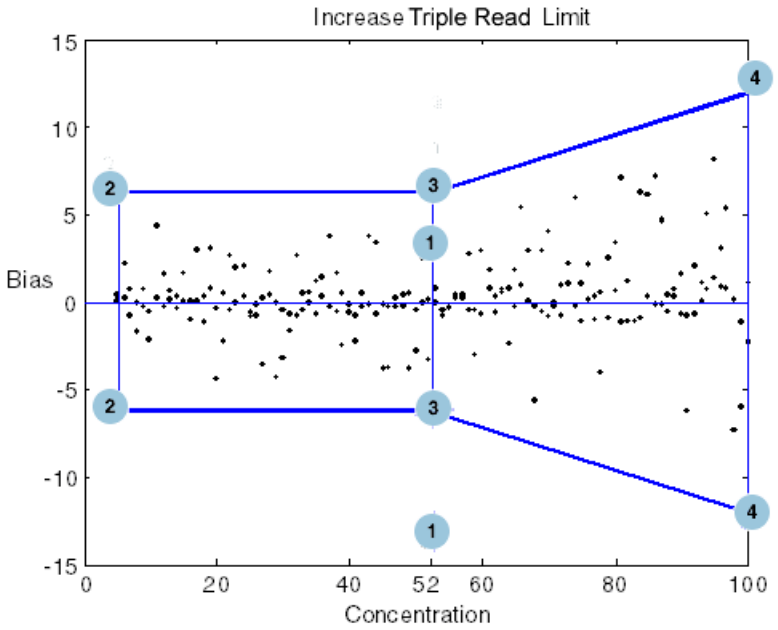
The triple read limits are the allowable bias defined at reportable minimum, critical concentration, and reportable maximum.

Bias in concentration = real concentration - predicted concentration

- The critical concentration can be adjusted by inputting a concentration value in the reportable range. The critical concentration is the point at which medical decisions are made between normal and abnormal test results.
- The triple read limit corresponding to reportable minimum must be a bias in concentration value.
- The triple read limit corresponding to critical concentration is defined as a percentage of the critical concentration.
- The triple read limit corresponding to reportable maximum is defined as a percentage of the reportable maximum.

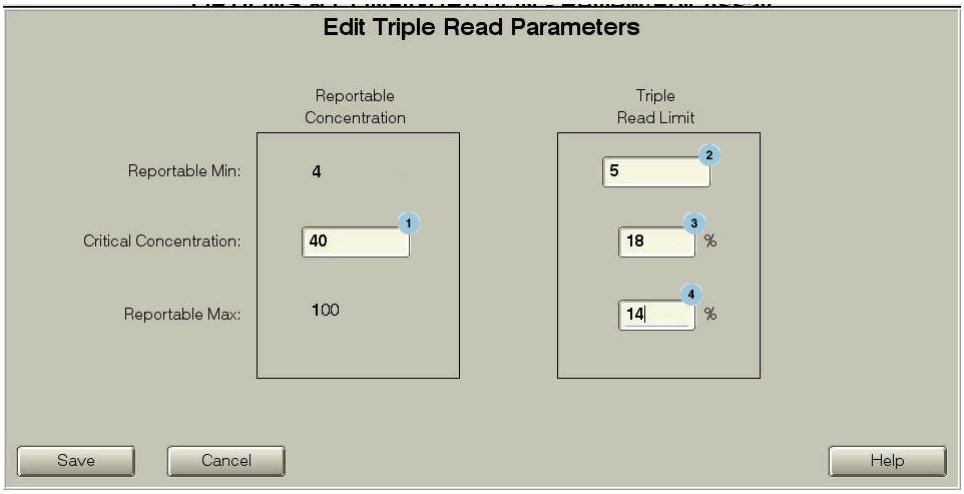
The following figures illustrate a relaxed triple read limit across the reportable range.:

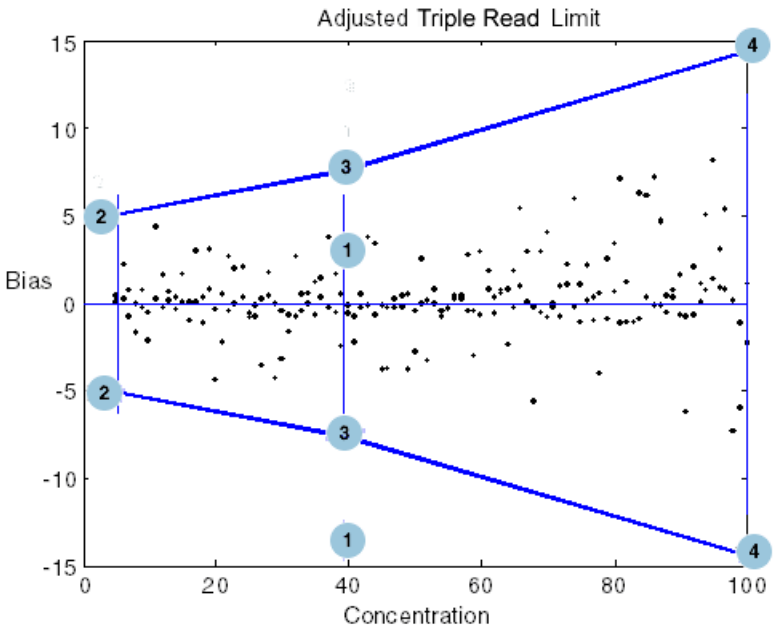




1	Critical value = Default
2	Bias at Min value = [Critical] · (12/100) = 6.25
3	Bias at Critical value = [Critical] · (12/100) = 6.25
4	Bias at Max value = [Max] · (12/100) = 12.0

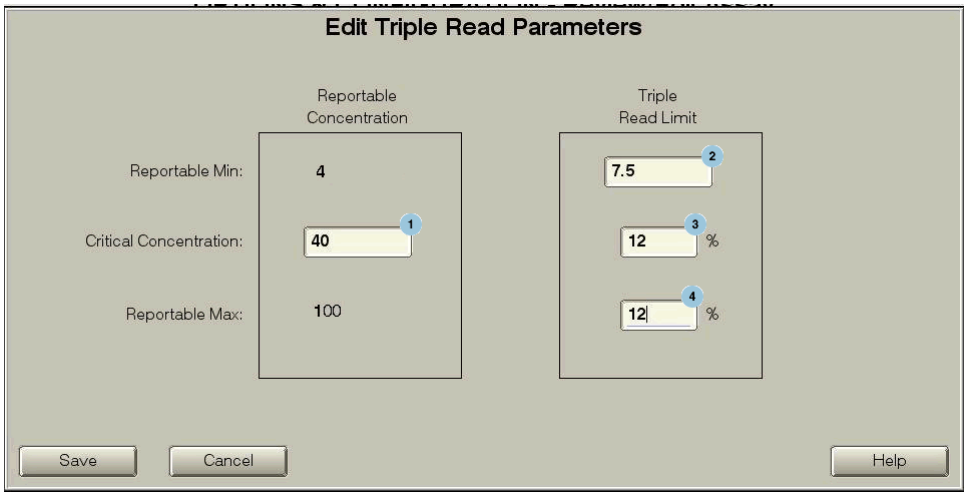
The following two figures illustrate adjusted triple read limits with a different critical concentration.

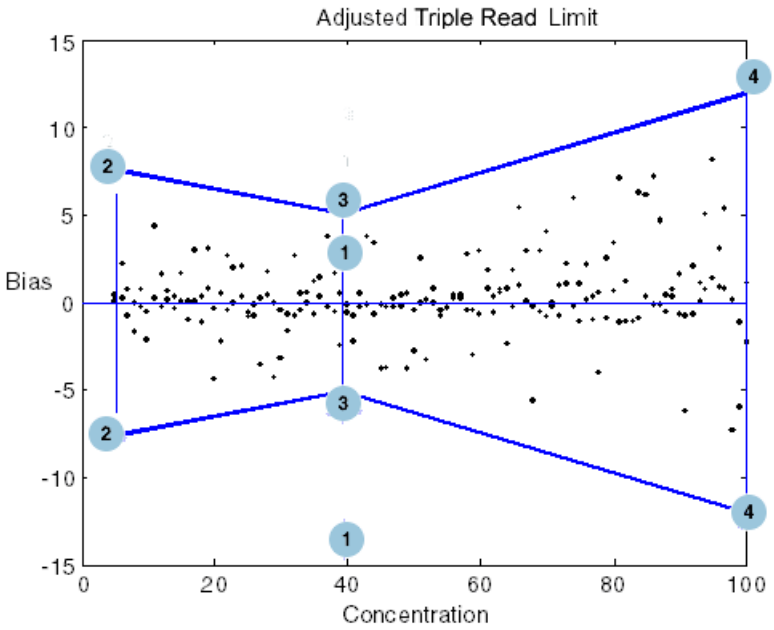




1	Critical value defined at 40
2	Bias at Min value defined as 5
3	Bias at Critical value = [Critical] · (18/100) = 7.2
4	Bias at Max value = [Max] · (14/100) = 14.0

The following figures illustrate an adjusted triple read limit with a different critical concentration and a higher bias limit at reportable minimum than the bias limit at the critical concentration..:





1	Critical value defined at 40
2	Bias at Min value defined as 7.5
3	Bias at Critical value = [Critical] · (12/100) = 4.8
4	Bias at Max value = [Max] · (12/100) = 12

Appendix A: Quick Reference Table

VITROS 5,1 FS UDA Guidelines

Item	Requirements
Available fluid types	• Serum/Plasma • Cerebral Spinal Fluid (CSF) • Urine • Whole Blood (hemolysate only)
Assay Model Type	• End Point Templates: — EPT1 R1-S — EPT1 R1-S-R2 — EPT1 R1-R2-S — EPT2 R1-S — EPT2 R1-S-R2 — EPT2 R1-R2-S • Two-point Rate Templates: — 2PT1 R1-S — 2PT1 R1-S-R2 — 2PT1 R1-R2-S • Two-point with Antigen Excess Rate Check Templates: — 2PTAE R1-S — 2PTAE R1-S-R2 — 2PTAE R1-R2-S • Multi-point Rate Templates: — NPT1 R1-S — NPT1 R1-S-R2 — NPT1 R1-R2-S
Calibration models and levels	• Linear Regression (2 levels minimum) • Cubic Spline (4 levels minimum) • Logit/Log4 (5 levels minimum) • Logit/Log5 (6 levels minimum)
Sample volume range	2 – 60 µL in 0.1 µL increments
Cuvette volume range	150 – 250 µL
Reagent volume ranges	R1: 30 – 200 µL R2: 9 – 110 µL All reagent volumes are defined in 0.1 µL increments

Item	Requirements
Reagent pack and diluent pack volumes	IMPORTANT:Use only VITROS 5, 1 FS reagent packs. **Bottle** / **Recommend Maximum Fill Volume** / **Dead volume** A: 15 mL: 1.7 mL B: 15 mL: 0.4 mL **CAUTION:Overfilling reagent pack bottles may create bubbles, foam, and form a thin film, preventing the system from operating correctly. Never fill over bottom of neck.**
Dilution factors	Supported dilution factors are 1 (for non-diluted samples), 1.3 – 100.
Minimum total mix volume	96 µL
Temperatures	Reagent storage temperature in SUPPLY 3 is 9°C ± 2°C Cuvette incubator reaction temperature is 37°C
Wavelengths	The following wavelengths are provided for assay evaluation: 340 nm, 510 nm, 620 nm 380 nm, 540 nm, 660 nm 405 nm, 575 nm, 700 nm 450 nm, 600 nm, 800 nm
Absorbance range	The acceptable absorbance range of the PHOTOMETER is -0.2 to 2.7 AU (absorbance units)
Calibration flags	You can set flags for: • Decreasing Monotonicity • Increasing Monotonicity • Increasing Rate
Total assay run time	1800 seconds (30 minutes) on the system
Earliest read time after fluid addition	9.5 seconds
UDA naming conventions	Supported UDA name lengths: • Long name: 20 alphanumeric characters • Short name: 5 alphanumeric characters

Appendix B: User Defined Assay Worksheet

NOTE: Fields that are gray are not required.

IMPORTANT: Fields that are not gray require an entry to initiate UDA processing.

Full Assay Name:		Fluid Type:			
Short Assay Name:		Template:			
Assay Model Type:		Calibrator Bottles:			
Cal Model Type:		Reagent Reps per Cal:			

Result Parameters

Units:		Significant Digits:		User Adjusted Slope:	
		Precision Digits:		User Adjusted Intercept:	
CuveTip Expiration Time:		Temperature Sensitive (yes/no):			
Reference Range:	to	Supplementary Range:	to	Reportable Range:	to
Initial Absorbance Limits:		Second/Blank Absorbance Limits:		Early Rate Read Index:	
Antigen Excess Factor:		Antigen Excess Limit:		Nonlinearity Limit:	
Increasing Rate Flag (yes/no):		Max Relative SD of Regression Line:			
Min. Read Points Allowed:		Max SD of Regression Line:			

Dilution Parameters

Diluent:		Standard Dilution Factor:			
Reflex Dilution (on/off):		Reflex Dilution Factor:		Reduction Factor:	

Calibration Parameters NOTE: Not required if user calibrating assay.

Kit Lot:					
	Bottle Number	Dilution Factor	Calibrator Replicate Response Range	Calibrator Value	
	1				
	2				
	3				
	4				

	5				
	6				
More Cal. Parameters					
Monotonicity:		Max. Response High:		Max Response Low:	
Cal. Fit Goodness Limit:		Min Response High:		Min Response Low:	
Protocol Parameters					
	Reagent				
Step	Volume	Pack Name	Sample Volume	Incubation Time	Read Wavelength
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					

27					
28					
29					
30					
Reagent Lot Information					
On Board Stability:		Reagent Lot Number:		Shelf Expiration Date:	
Triple Read Parameters					
Critical Concentration:					
Reportable Concentration:		Reportable Min Triple Read Limit:			
		Critical Concentration Triple Read Limit:			
		Reportable Max Triple Read Limit:			

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Appendix C: Worksheet Key

User Defined Assays Main Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Assay Button		1-20 (Assay IDs 980-999)
Full Assay Name		Up to 20 characters
Short Assay Name		Up to 5 characters
Fluid Type	Serum	Serum Urine CSF Whole Blood (Hemolysate)
Assay Model Type	None	None 2 Point Rate 2 Point with Antigen Excess Rate Check End Point Multi Point
Template	2PT R1-R2-S R1 = Reagent 1 R2 = Reagent 2 S = Sample Listed in order of addition	2PT R1-R2-S 2PT R1-S 2PT R1-S-R2 2PTAE R1-R2-S 2PTAE R1-S 2PTAE R1-S-R2 EPT1 R1-R2-S EPT1 R1-S EPT1 R1-S-R2 EPT2 R1-R2-S EPT2 R1-S EPT2 R1-S-R2 NPT R1-R2-S NPT R1-S NPT R1-S-R2

User Defined Assays Main Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Calibration Model Type	Logit/Log4	Logit/Log4 Linear Logit/Log5 Cubic Spline
Calibrator Bottles		1 to 6
Reagent Reps per Cal		1 to 40

Edit Result Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Units		
Significant Digits	6	1 to 6
Precision Digits	3	0 to 3
User Adjusted Slope	1.0	-999999000 to 999999000 0 is not allowed
User Adjusted Intercept	0.0	-900000000 to 900000000
CuveTip Expiration Time	35	5 to 35 minutes in 5 minute increments
Temperature Sensitive	Disabled	Disabled or Enabled
Reference Range	0 to 900000000	0 to 900000000
Supplemental Range	0 to 900000000	0 to 900000000
Reportable Range	0 to 10000	-900000000 to 900000000

Edit Result Additional Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Initial Absorbance Limits	-0.200 to 2.700	-0.200 to 2.700 2 Point Rate, 2 Point with Antigen Excess Rate Check, End Point, Multi Point
Second Absorbance Limits	-0.200 to 2.700	-0.200 to 2.700 2 Point Rate, 2 Point with Antigen Excess Rate Check
Blank Absorbance Limits	-0.200 to 2.700	-2.000 to 2.700 End Point

Edit Result Additional Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Antigen Excess Factor	9.0000	0.0000 to 10.0000 2 Point Rate, 2 Point with Antigen Excess Rate Check
Early Rate Read Index	1	1 to 3 2 Point with Antigen Excess Rate Check
Antigen Excess Limit	9.0000	0.0000 to 10.0000 Multi Point
Nonlinearity Limit	0.1000	0.0000 to 1000.0000 Multi Point
Increasing Rate Flag	Enabled	Enabled or Disabled Multi Point
Max Relative SD of Regression	100.000	0.00 to 100.0000 Multi Point
Minimum Read Points Allowed	3	2 to 12 Multi Point
Max SD of Regression Line	10.000	0 to 10 Multi Point

Edit Dilution Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Diluent:	None	None Saline BSA Water Specialty Urine Electrolyte Diluent (UED) ApoDiluent User Defined Diluents
Standard Dilution Factor	1.0 (no dilution)	1.0, 1.3 to 100.0 in 0.1 increments
Reflex Dilution	Off	Off or On

Edit Dilution Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Dilution Factor	1.0 (no dilution)	1.0 to 100.0 in 0.1 increments
Reduction Factor	1.0	0.1 to 1.0 in 0.1 increments

Edit Calibration Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Dilution Factor	1.0 (no dilution)	1, 1.3 to 100
Calibrator Replicate Response Range	0.20000	0 to 0.2
Kit Lot		1 to 99
Calibrator Value		-900000000 to 900000000

Edit Calibration Additional Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Monotinicity	Increase	Increase or Decrease
Max Response High	3.00	-1000 to 1000
Max Response Low	-3.00	-1000 to 1000
Min Response High	3.00	-1000 to 1000
Min Response Low	-3.00	-1000 to 1000
Cal Fit Goodness Limit	0.99	0.000 to 1.000 For Cal Model Types: Linear, Logit/Log4, Logit/Log5

Edit Protocol Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Protocol - Reagent (R1) Volume (µL)	150.0	30.0 to 200.0
Protocol - Reagent (R1) Pack Name/ Bottle	Template dependent	UD01 (A or B) to UD10 (A or B)
Protocol - Reagent (R2) Volume (µL)	10.0	9.0 to 110.0
Protocol - Reagent (R2) Pack Name/ Bottle	Template dependent	UD01 (A or B) to UD10 (A or B)
Protocol - Sample Volume (µL)	5.0	2.0 to 60.0
Protocol - Incubation Time (seconds)	Template dependent	Template dependent

Edit Protocol Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Protocol - Read Wavelength (nm)	340 for end point and rate reads. 540 for blank reads.	None 340.....510.....620 380.....540.....660 405.....575.....700 450.....600.....800

Reagent Lot Information Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
On Board Stability (Days)		1 to 99
Reagent Lot Number		Any Printable Character
Shelf Expiration Date		

Edit Triple Read Parameters Screen		
Parameter	**Default**	**Ranges/Limits/Available Options**
Critical Concentration Reportable Concentration	Midpoint between the Reportable Range	-900000000 to 900000000
Reportable Min Triple Read Limit	Critical Concentration · 8%	>0 to 900000000
Critical Concentration Triple Read Limit	8%	0.1 to 1000 percent in 0.1 increments
Reportable Max Triple Read Limit	8%	0.1 to 1000 percent in 0.1 increments

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Appendix D: Molar Extinction Coefficient

UDA Molar Extinction Coefficient Guidelines

The Cal Model Type of Linear must be selected when first setting up the UDA.

UDA features that require input are:

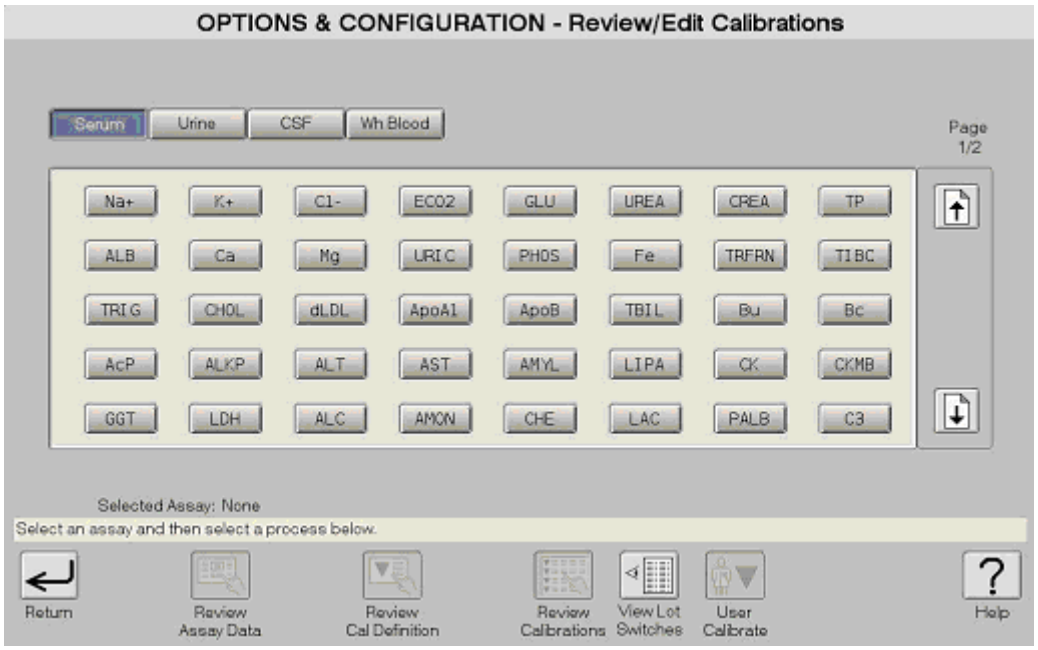
- Reagent Lot information
- Result Parameters
- Protocol Parameters

NOTE: Cal Params do not require input.

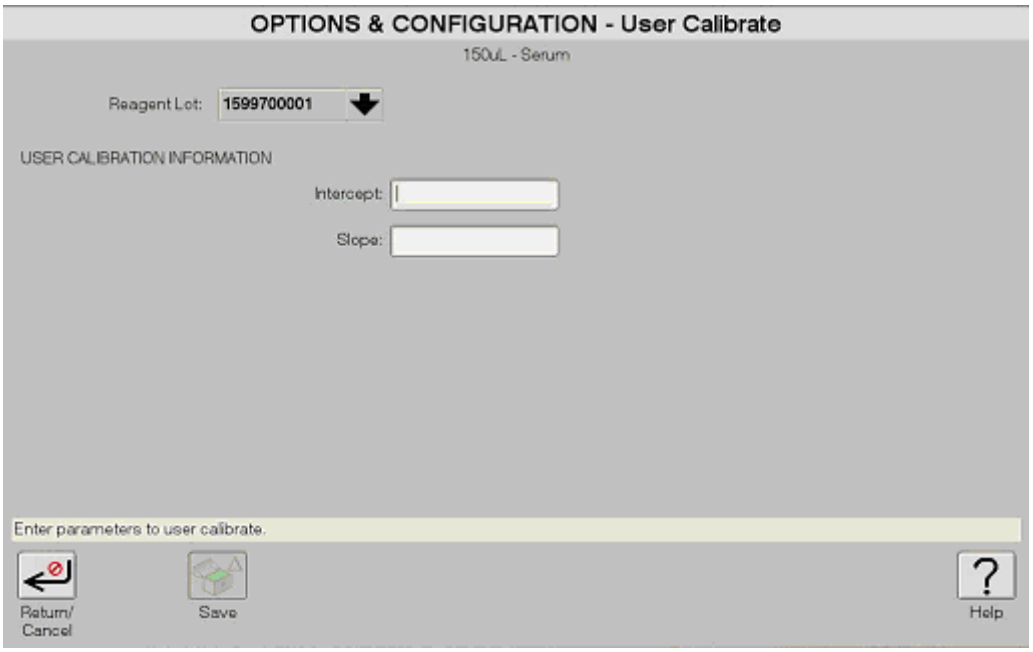
1. After appropriate parameters have been entered, Touch Reagent Management and load the UDA reagent pack.

NOTE: If no reagent is loaded for the assay, you cannot access the User Calibrate screen.

2. On the Options and Configuration screen, touch Review/Edit Calibrations.



3. On the Review/Edit Calibrations screen, select the UDA assay then touch User Calibrate.



4. Select the Reagent Lot (Reagent pack lot number) from the drop down box.
5. Input the intercept and slope.[1]
6. Touch the Save button to save your changes.

NOTE: Results reported will display a “UC” code notifying the user that the result is based on a User Calibration.

1. Intercept = Response when distilled water is run as a sample.
   Slope = (Sv * ME) / (Tv * 1000 mL/L* DIL)
   Sv = Sample volume (mL)
   ME = Molar Extinction coefficient in $cm^2/\mu mol$
   (example: NADH = 6.25 at 340nm)
   Tv = Total reaction volume (mL) (sample + reagent)
   DIL = Dilution factor of sample prior to being added to cuvette.

NOTE: Results from above calculations are either in µmol/min or µmol/L.

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CE IVD

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