

IDEXX xChek*: Creating a User-Defined Assay for the IDEXX* *Mycobacterium paratuberculosis* Antibody ELISA—Serum/Plasma (U.S.)

Creating a user-defined assay is an easy process of two tasks—editing an xChek file to allow you to create an assay, and then creating the assay within xChek.

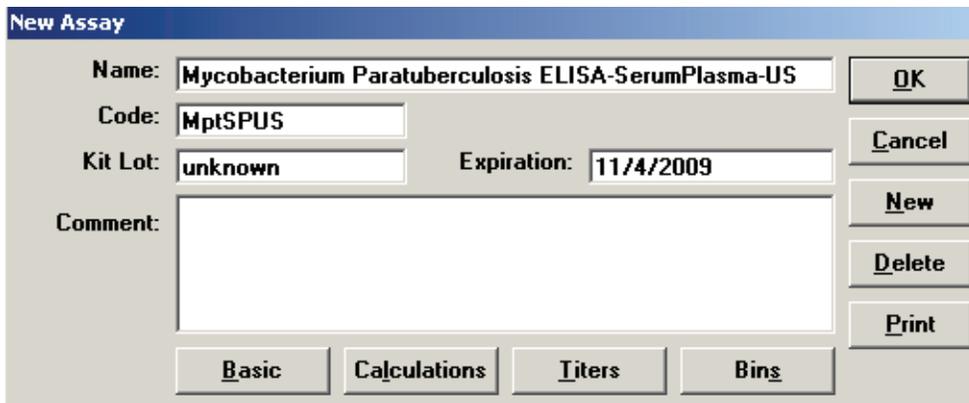
To edit the xChek.ini file:

1. From the task bar, choose **Start> Run** and type “xchek.ini” into the text box. Click the **OK** button.
2. After the xChek.ini file opens, locate the line labeled “AllowNewAssays.”
3. If the value for that line is “0,” change it to “1.” If the value is already “1,” do not do anything.
4. Locate the section labeled “BasicGraphs” and scroll to the end of the section.
5. Enter “MptSPUS=11.”
6. From the menu bar, choose **File> Save**, and then choose **File> Exit**.

To create the assay:

1. From the task bar, choose **Start> Programs> xChek> xChek** to open the xChek program.
2. From the menu bar, choose **Database> Assays> All** to open the Assay dialog box.
3. Click the **New** button, and enter “Mycobacterium Paratuberculosis ELISA-SerumPlasma-US” into the Name field, “MptSPUS” into the Code field, and “unknown” into the Kit Lot field. Today’s date (mm/dd/yyyy) is automatically entered into the Expiration field.

NOTE: When you begin testing, update the information in the Kit Lot and Expiration fields with the actual kit lot number and expiration date.



4. Click the **Basic** button, and select or enter the following information for the respective fields:

Case Type: Animal	Samp Filter: 450
Template: Johnes Ab Vert	Ref. Filter: 0
Species: Cattle	Dilution: 20
Technology: ELISA	Wells: 1



- Click **OK** to save the settings.
- Click the **Calculations** button, and select or enter the following information:

Formulas:

“S” Part of Ratio: Sample1 - Negative

“P” Part of Ratio: Positive - Negative

“N” Part of Ratio: None

Blocking Factor: None

First Calculation:

Variable: S/P

Positive Cutoff: 0.7

Suspect Cutoff: 0.6

Comparison: >=

Second Calculation:

Variable: None

Positive Cutoff: 0

Suspect Cutoff: 0

Comparison: None

- Click **OK** to save these settings, and then click the **OK** button to save the assay to the database. You can now test for Paratuberculosis antibodies using the xChek Assay Management System.

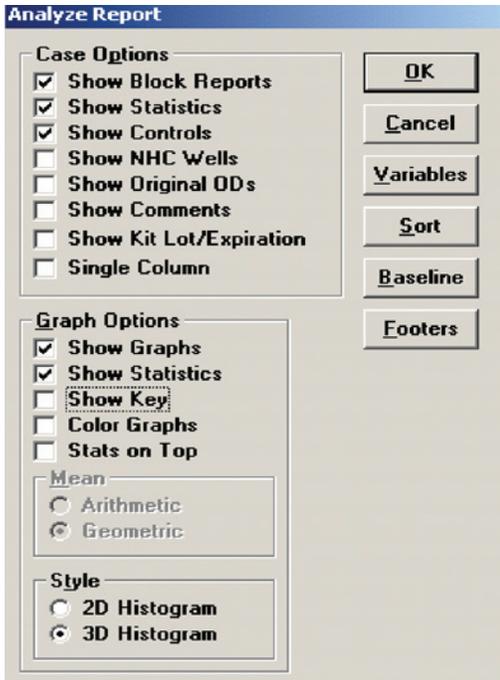
NOTE: xChek does not evaluate controls or results for validity when you use a user-defined assay. You must evaluate the results from each assay in accordance with good laboratory practices. To evaluate your assay validity, refer to the “Interpretation of Results” section in the insert provided with the test kit.

Setting Up Additional Display Variables

Only OD values are displayed in the reporting options for this user-defined assay. To set up additional display variables, follow the directions below.

- From the xChek menu bar, choose **Reports > Analyze Cases** to open the Filter Criteria for Analyze dialog box.
- Enter the desired search criteria and click **OK**. The Select Cases for Analyze dialog box appears.

3. Select the desired cases and click **OK**. The Analyze Report dialog box appears.

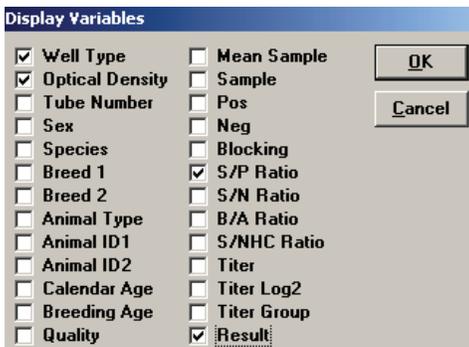


The **Analyze Report** dialog box is shown with the following options:

- Case Options:**
 - Show Block Reports
 - Show Statistics
 - Show Controls
 - Show NHC Wells
 - Show Original ODs
 - Show Comments
 - Show Kit Lot/Expiration
 - Single Column
- Graph Options:**
 - Show Graphs
 - Show Statistics
 - Show Key
 - Color Graphs
 - Stats on Top
- Mean:**
 - Arithmetic
 - Geometric
- Style:**
 - 2D Histogram
 - 3D Histogram

Buttons on the right: **OK**, **Cancel**, **Variables**, **Sort**, **Baseline**, **Footers**.

4. Click the **Variables** button to open the Display Variables dialog box.



The **Display Variables** dialog box is shown with the following options:

<input checked="" type="checkbox"/> Well Type	<input type="checkbox"/> Mean Sample
<input checked="" type="checkbox"/> Optical Density	<input type="checkbox"/> Sample
<input type="checkbox"/> Tube Number	<input type="checkbox"/> Pos
<input type="checkbox"/> Sex	<input type="checkbox"/> Neg
<input type="checkbox"/> Species	<input type="checkbox"/> Blocking
<input type="checkbox"/> Breed 1	<input checked="" type="checkbox"/> S/P Ratio
<input type="checkbox"/> Breed 2	<input type="checkbox"/> S/N Ratio
<input type="checkbox"/> Animal Type	<input type="checkbox"/> B/A Ratio
<input type="checkbox"/> Animal ID1	<input type="checkbox"/> S/NHC Ratio
<input type="checkbox"/> Animal ID2	<input type="checkbox"/> Titer
<input type="checkbox"/> Calendar Age	<input type="checkbox"/> Titer Log2
<input type="checkbox"/> Breeding Age	<input type="checkbox"/> Titer Group
<input type="checkbox"/> Quality	<input checked="" type="checkbox"/> Result

Buttons on the right: **OK**, **Cancel**.

5. Select the desired options and click **OK**. Click **OK** again to save the settings.

For more information, call IDEXX Technical Service at 1-800-548-9997 or visit us on the web at idexx.com.



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