IDEXX xChek*: Creating a User-Defined Assay for the Pourquier* Paratuberculosis Antibody Verification ELISA – Serum/Plasma (OUS)

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 then 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 line labeled "Basic Graphs," and scroll to the end of the section.

5. Enter "MptvSPOUS=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 then enter "Pourquier Paratuberculosis Verif ELISA Serum Plasma OUS" into the Name field, "MptvSPOUS" 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 then select or enter the following information for the respective fields:

Case Type: Animal	Samp Filter: 450
Template: BLVv Vert	Ref. Filter: 0
Species: Cattle	Dilution: 20
Technology: ELISA	Wells: 2

NOTE: The Pourquier paratuberculosis assay has a negative and a positive control configuration in the insert that is not supported by the IDEXX xChek software. The assay has been set up in xChek to have a vertical control configuration. Therefore, place negative controls in wells A1, A2, B1, and B2 and positive controls in wells C1, C2, D1, and D2.

5. Click **OK** to save the settings.

6. Click the **Calculations** button, and then select or enter the following information:

Formulas:

       "S" Part of Ratio: Sample 2 - Sample 1

       "P" Part of Ratio: Positive 2 - Positive 1

       "N" Part of Ratio: None

       Blocking Factor: None

First Calculation: Second Calculation:

       Variable: S/P   Variable: None

       Positive Cutoff: 0.550   Positive Cutoff: 0

       Suspect Cutoff: 0.451   Suspect Cutoff: 0

       Comparison: >=   Comparison: None

NOTE: xChek does not support the S/P % calculation. Instead, xChek calculates an S/P value. The cutoff values have been updated to match the new calculation, and the interpretation is the same.

7. Click **OK** to save these settings, and then click **OK** 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 "Validation Criteria" 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.

1. From the xChek menu bar, choose **Reports> Analyze Cases** to open the Filter Criteria for Analyze dialog box.

2. 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.

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

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

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