

IDEXX xChek*: Creating a User-Defined Assay for the IDEXX Bovine Pregnancy Test—with Optional Pregnant-Recheck Zone

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 software.

To edit the xChek.ini file:

1. From the task bar, choose **Start> Run**, and type “xchek.ini” into the text box. Click **OK**.
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 “Pregnancy=17.”
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. If prompted to log in, enter your initials and then click **OK**.
3. From the menu bar, choose **Database> Assays> All** to open the Assay dialog box.
4. Click the **New** button, and enter “IDEXX Bovine Pregnancy Test” into the Name field, “Pregnancy” 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.

The screenshot shows the 'New Assay' dialog box with the following fields and values:

- Name: IDEXX Bovine Pregnancy Test
- Code: Pregnancy
- Kit Lot: unknown
- Expiration: 8/3/2010
- Comment: (empty text area)

Buttons on the right: OK, Cancel, New, Delete, Print.

Buttons at the bottom: Basic, Calculations, Titer, Bins.

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

Case Type: Animal	Samp Filter: 450
Template: Neo Vert	Ref. Filter: 620
Species: Cattle	Dilution: 1
Technology: ELISA	Wells: 1

Note: Refer to the package insert for acceptable reference ranges for reference filter wavelengths.

The screenshot shows the 'New Assay' dialog box with the 'Basic' tab selected. The fields are:

- Case Type: Animal
- Template: NEO Vert
- Species: Cattle
- Technology: ELISA
- Samp Filter: 450
- Ref Filter: 620
- Dilution: 1
- Wells: 1

Buttons on the right: OK, Cancel.

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

Formulas:

“S” Part of Ratio: Sample1-Negative
 “P” Part of Ratio: None
 “N” Part of Ratio: None
 Blocking Factor: None

First Calculation:

Variable: S
 Positive Cutoff: 1.000
 Suspect Cutoff: 0.300
 Comparison: >=

Second Calculation:

Variable: None
 Positive Cutoff: 0
 Suspect Cutoff: 0
 Comparison: None

8. Click **OK** to save these settings, and then click **OK** to save the assay to the database. You can now test for pregnancy status using the xChek Assay Management System.

Please note that results within the range of 0.300 and 1.000 will be reported as suspect with the software but will be considered “Pregnant-Recheck”. IDEXX has updated the BPT Product Insert with the following recommendation:

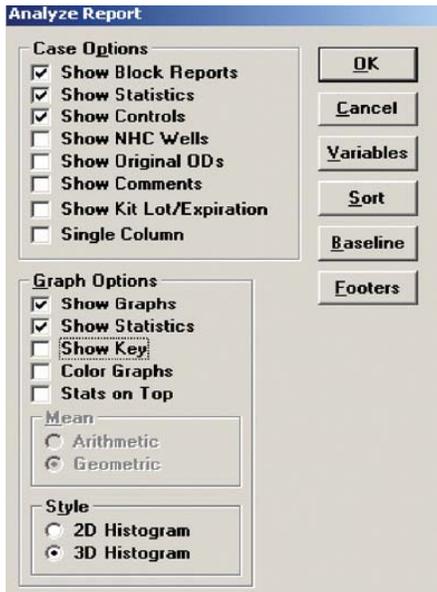
“Pregnant-Recheck: Embryonic death is common in early stages of cow pregnancy. PAGs can circulate in cows/heifers for some time after early embryonic death. An optional recheck of the animal is recommended if the S-N value is equal to or greater than 0.300 and less than 1.000. IDEXX encourages producers to work closely with their veterinarian to develop a reproductive management program that is appropriate for their operation.”

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 “Results” section in the insert provided with the test.

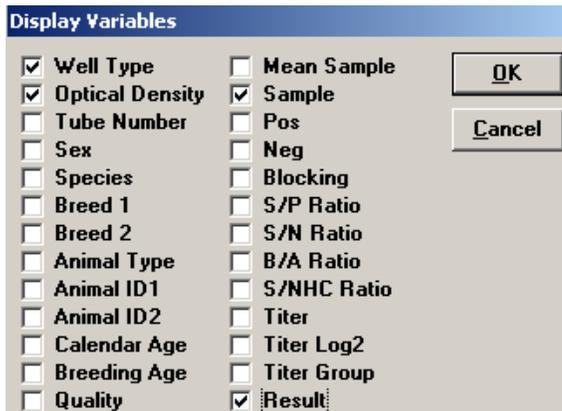
Setting Up Additional Display Variables

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



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.



For more information, call IDEXX Technical Services at 1-800-548-9997 (in the U.S.) or 1-207-556-4895 (outside of the U.S.), or visit us on the web at idexx.com.

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