ANTIGEN CONCENTRATION: A dose response curve is used to ascertain the concentration of progesterone in unknown specimens.

1. Record the RLUs obtained from the printout of the microplate reader as outlined in Example 2.
2. Plot the RLUs for each duplicate serum reference versus the corresponding Progesterone concentration in ng/ml on linear graph paper.
3. Draw the best-fit curve through the plotted points.
4. To determine the concentration of Progesterone for an unknown, locate the average RLU’s for each unknown on the best-fit curve. The corresponding Progesterone concentration in ng/ml can be obtained from the corresponding point on the y-axis of the best-fit curve.

Note: Computer data reduction software designed for chemiluminescence may also be used for the data reduction. If such software is utilized the validation of the software should be utilized.
11.0 Q.C. PARAMETERS

In order for the assay results to be considered valid the following criteria should be met:

1. The Dose Response Curve should be within established parameters.

2. Four out of six quality control pools should be within the established ranges.

12.0 RISK ANALYSIS

The MSDS and Risk Analysis Form for this product is available upon request from Monobind Inc.

12.1 Assay Performance

It is important that the time of reaction in each well is held constant to achieve reproducible results.

2. Pipetting of samples should not extend beyond ten (10) minutes to avoid deterioration.

3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.

4. If more than one Tietz test is used, it is recommended to repeat the dose response curve.

5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.

6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.

7. Use components from the same lot. No intermixing of reagents from different batches.

8. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed, are essential. Any deviation from Monobind's IFU may yield inaccurate results.

9. Patients with Progesterone levels higher than 60ng/ml may be diluted (1:5 or 1:10) with progesterone '0 ng/ml' calibrator or male patient serum pools with a known low value for progesterone.

10. All applicable national standards, regulations and laws, including, but not limited to, good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.

11. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventative maintenance.

12. Risk Analysis - as required by CE Mark (1998/79/EC) for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.


Revision: 5 Date: 060402

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Cat #: 4875-300

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