Validation of a New and Improved Progesterone Assay on the IMMULITE Immunoassay System


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Abstract

Background: Progesterone is a steroid hormone essential in the preparation for and maintenance of pregnancy in both the female and male. Bioavailability and stability are important considerations for the development of a new assay. This article describes a new assay with novel characteristics that improves on existing assays.

Materials and Methods: The assay design is based on a competitive immunoassay format. Progesterone in patient sample competes with progesterone conjugate to label for a limited amount of antibody-coated beads.

Results: For the method comparison performed at one site with the two lot assay on IMMULITE Progesterone Assay (LKPW1 203) with 168–172 individual subject serum samples, the slope 0.988 with a correlation coefficient of 0.99. As shown in Figure 3.

Conclusions: The results presented in Figures 2 and 3 support the conclusion that the new Progesterone Assay for the IMMULITE and IMMULITE 1000, 2000, and 2000 XPi Systems provide improved clinical performance over the former assay, is comparable to the IMMULITE 2000/2000 XPi Progesterone Assay.

References:

Acknowledgments:
The authors would like to recognize the excellent technical contributions for this project from Ms. Lise Lou Berrevoets, and Nairy Alhaj from Siemens Healthcare Diagnostics Inc. in Tarrytown, New York.

CRED (Collaborative Research for Effective Diagnostics) is a multidisciplinary research team that has developed high standards in evaluation protocols and procedures for diagnostic tests.

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Background

Progesterone levels vary throughout the menstrual cycle and multiple assessments may be used to help identify and manage issues causing potential complications during pregnancy. If a woman ovulates, her estrus levels may be monitored by the follicular phase and estradiol levels, and the luteal phase level of the menstrual cycle in females. Measurement of serum progesterone may provide valuable information on the adequacy of the menstrual cycle, ovulation, and luteal phase function. The concentrations of progesterone in the sera are valid conclusions in ovulation induction and aid in determining patients at risk for abortion. As shown in Figure 3.

Materials and Methods

The test design is based on a competitive immunoassay format. Progesterone in patient sample competes with progesterone conjugate to label for a limited amount of antibody-coated beads. The antibody-coated beads are then removed by a centrifugal wash. Finally, the progesterone conjugated to bovine calf intestine alkaline phosphatase for binding to the progesterone antiserum, and a reagent containing progesterone conjugated to bovine calf intestine alkaline phosphatase (Progesterone-AP) conjugate. As shown in Figure 1.

Results

This method replaced the former two-cycle Progesterone assay (LKPG) on the IMMULITE family of systems. Counts Per Second (CPS), as shown in Figure 3.

Conclusions

The results presented in Figures 2 and 3 support the conclusion that the new Progesterone Assay for the IMMULITE and IMMULITE 1000, 2000, and 2000 XPi Systems provide improved clinical performance over the former assay, is comparable to the IMMULITE 2000/2000 XPi Progesterone Assay.

Figure 1: Schematic diagram of the IMMULITE Progesterone assay format.

Figure 2: Method comparison of three IMMULITE Progesterone assays (LKPW 201, LKPW 202, and LKPW 203) vs. IMMULITE 2000 Progesterone Assay at one testing site (Tarrytown, NY).

Figure 3: Method comparison of the IMMULITE Progesterone assay (LKPW 203) vs. the IMMULITE 2000 Progesterone assay at one testing site (Tarrytown, NY).