Dimension Vista LOCI Progesterone Assay Specifications

www.siemens.com/diagnostics

Assay Specifications
The LOCI® progesterone assay is an in vitro diagnostic test for the quantitative measurement of progesterone in human serum and plasma on the Dimension Vista® Systems.

Clinical Utility
Progesterone measurements are used in the diagnosis and treatment of disorders of the ovaries or placenta. Progesterone is a steroid hormone synthesized from cholesterol mostly in the ovary and placenta of females, and in small amounts in the adrenal cortex of both sexes. Progesterone and estradiol are responsible for preparing the uterine endometrium for implantation of a fertilized egg and maintaining a fetus through pregnancy. Progesterone also affects a wide range of other tissues, such as the brain and immune system.

Progesterone levels are used to detect luteal phase defects leading to infertility and early loss of pregnancy.

Decreased progesterone levels are seen in ovarian (primary) hypofunction in pre-menopausal and menopausal females. Lesions in the hypothalamic-pituitary axis also can cause low progesterone in both sexes. Progesterone levels are normally low in males. Elevated progesterone levels are seen in the second half of the menstrual cycle and during pregnancy.

The addition of LOCI® Progesterone complements our fertility assays on Dimension Vista systems, including FSH, LH, estradiol, HCG, and prolactin. The LOCI fertility methods offer your laboratory the following benefits:
Best-in-class technology for confidence in results:
• High-sensitivity/excellent precision
• Minimal sample volume
• Fewer redraws
• Wide assay ranges reduce needed dilutions

Maximum workflow integration for easier consolidation of tasks:
• Long onboard assay and calibration stability
• Serum and plasma capable
• Wide range of assays
• All testing from one tube at one time
• Uncompromised throughput regardless of testing mix and volume
Dimension Vista LOCI Progesterone Assay Specifications

The Dimension Vista LOCI fertility assays help you consolidate your fertility and chemistry testing onto one system, leading to increased workflow efficiency and reduced operational costs.

### Dimension Vista LOCI Progesterone Performance Summary

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Sample Volume</th>
<th>Assay Range</th>
<th>Limit of Blank</th>
<th>Limit of Detection</th>
<th>Calibration Interval</th>
<th>Onboard Stability</th>
<th>Time to First Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum or plasma (heparin, EDTA)</td>
<td>10 µL</td>
<td>0.200–40.0 ng/mL (0.636–127 nmol/L)</td>
<td>0.10 ng/mL (0.32 nmol/L)</td>
<td>0.20 ng/mL (0.64 nmol/L)</td>
<td>7 days</td>
<td>30 days</td>
<td>21 min</td>
</tr>
</tbody>
</table>

### Ordering Information

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>SMN No.</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>K6464</td>
<td>10461743</td>
<td>LOCI PROG Flex® reagent cartridge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 tests/well, 80 tests/flex, 320 tests/carton (4 flexes)</td>
</tr>
<tr>
<td>KC637</td>
<td>10712610</td>
<td>PROG Calibrator (3 x 5 levels)</td>
</tr>
<tr>
<td>KD694</td>
<td>10483586</td>
<td>MULTI 2 SDIL (6 x 2.5 mL/vial)</td>
</tr>
</tbody>
</table>

### References:

1. Siemens Instructions For Use

### Method Comparisons

The Dimension Vista progesterone assay was compared to ID-GC/MS using 42 patient samples.

- **Slope:** 1.02
- **Intercept:** 0.46
- **Correlation coefficient:** 0.99
- **n:** 42
- **Min:** 0.248 ng/mL [0.789 nmol/L]
- **Max:** 38.4 ng/mL [122 nmol/L]

The Dimension Vista progesterone assay was compared to Roche ELECSYS progesterone using 179 patient samples.

- **Slope:** 0.93
- **Intercept:** 0.16
- **Correlation coefficient:** 0.99
- **n:** 179
- **Min:** 0.201 ng/mL [0.639 nmol/L]
- **Max:** 39.8 ng/mL [127 nmol/L]

Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

Dimension Vista, LOCI, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc. All other trademarks and brands are the property of their respective owners. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Global Siemens Headquarters
Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters
Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen, Germany
Phone: +49 9131 84 - 0
www.siemens.com/healthcare

Global Division
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
www.siemens.com/diagnostics

Order No. A91DX-CAI-131204-GC1-4A00
01-2014 | All rights reserved © 2014 Siemens Healthcare Diagnostics Inc.

www.siemens.com/diagnostics