

## MAKING A DIFFERENCE IN REPRODUCTIVE HEALTH

### Access Sensitive Estradiol Assay for Access Immunoassay Systems

Reproductive health concerns can affect people at all ages, and measuring hormone levels is key to addressing these concerns. Estradiol is a natural estrogen that is present in women and men. In non-pregnant women, estradiol is secreted by the ovary and the corpus luteum. In men, estradiol is primarily formed by aromatization of testosterone.

Levels of estradiol are used to monitor ovulatory status,<sup>1</sup> and, because estradiol levels reflect follicular maturation, the measurement of estradiol has been used as a valuable tool in the assessment of sexual development in children, anovulation and/or amenorrhea, polycystic ovary syndrome, and causes of infertility and menopause.<sup>2,3,4</sup>

For men, there is emerging evidence that estradiol levels play an important role in maintaining reproductive health and optimal bone density.

During *in vitro* fertilization, estradiol levels are routinely measured after gonadotropin stimulation to determine follicular status.<sup>5</sup>

The Beckman Coulter Access Sensitive Estradiol assay has the broadest measuring range, state-of-the-art sensitivity and is the only assay in the market to offer a pediatric reference range. This unique combination provides better operational efficiency, reduces costs and delivers the quality results to make a difference in patients' reproductive health.

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#### ● The Access Sensitive Estradiol assay will:

- › **Strengthen your confidence** in low-end results with state-of-the-art sensitivity
- › **Create efficiencies and reduce costly dilutions** with the broadest, dynamic range, which surpasses IVF hyper-response guidelines
- › **Ensure accurate patient results and proven correlation** to GC-MS, the gold standard for estradiol testing

## Access Sensitive Estradiol Assay: state-of-the-art sensitivity and broadest measuring range

### Performance characteristics

A comparison of 135 values using the Access Sensitive Estradiol assay on an Access Immunoassay System and mass spectrometry—including comparison to the ID/GC/MS reference measurement procedure (RMP) developed at Ghent University and an LC-MS method—gave the following statistical data. Analysis was performed using Passing-Bablok regression and Pearson's correlation, based on the CLSI EP09-A3 guideline.

N	Range of Observations (pg/mL)	Intercept (pg/mL) [95% CI]	Slope [95% CI]	Correlation Coefficient (r)
135	15.7 to 4,838	-2.957 [-8.46 to 0.63]	0.98 [0.95 to 1.00]	0.99

### Characteristics

Sample type/size	Serum, plasma (lithium heparin, sodium heparin, EDTA)/30 µL pick up
Time to first result	≤55 minutes
Limit of quantification (20% CV)	19.0 pg/mL (69.7 pmol/L)
Limit of detection	15.0 pg/mL (≤ 55.1 pmol/L)
Approximate calibrator levels	0, 11.0, 32.0, 292, 885 and 5,200 pg/mL (0, 40.4, 117, 1,072, 3,249 and 19,089 pmol/L)
Reportable measuring range	15.0–5,200 pg/mL (55.1–19,089 pmol/L)
Open-pack stability	28 days
Calibration stability	28 days
Precision	Total imprecision is ≤10% at concentrations >30.0 pg/mL (110.1 pmol/L), and total standard deviation (SD) is ≤5.00 pg/mL (18.36 pmol/L) at concentrations ≤30.0 pg/mL (110.1 pmol/L)

### Ordering information

Access Sensitive Estradiol Assay, 2 packs of 50 tests/pack	<b>B84493</b>
Sensitive Estradiol Calibrators S0, 4.0 mL/vial; S1–S5 2.0 mL/vial	<b>B84494</b>
Access Sensitive Estradiol Calibrator S0, 4.0 mL/vial	<b>B97145</b>

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|--------------|--------------|-----------------------|--------------------------|
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| › AMH        | › hLH        | › Progesterone        | › Testosterone           |
| › DHEA-S     | › Inhibin A  | › Prolactin           | › Total βhCG (5th IS)    |
| › Estradiol  | › Inhibin B* | › Sensitive Estradiol | › Unconjugated Estradiol |

Access Sensitive Estradiol assay is part of a comprehensive assay menu featured on Access and UniCel immunoassay systems. To learn more, visit [www.beckmancoulter.com/immunoassay](http://www.beckmancoulter.com/immunoassay).

### References

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- Access Sensitive Estradiol instructions for use (IFU). Beckman Coulter, Inc. 2017.

\*Available in ELISA format.

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