

May 5, 2009

Dear Valued Customer:

This is to notify you of an upcoming change to the **Estradiol HS EIA assay kit** (research use #1-3702/1-3702-5 and diagnostic use #1-4702/1-4702-5). The estradiol DILUENT has been reformulated to improve sensitivity of the assay. No changes have been made to any other reagents, assay protocol, performance or specificity.

Kits containing the new diluent will begin shipping near the end of June 2009. A release date will be posted on the Salimetrics website when the change occurs.

Saliva assayed for estradiol using OLD diluent and NEW diluent correlate very highly $[\underline{r}(54) = 0.99, \underline{p} < 0.001]$. As anticipated, there is a shift to lower expected MEAN values.

| OLD diluent | NEW diluent |
|------------------------|-------------------------|
| Sensitivity = <1 pg/mL | Sensitivity = 0.1 pg/mL |
| Mean = 12.63 pg/mL | Mean = 9.55 pg/mL |
| SD = 6.61 pg/mL | SD = 5.35 pg/mL |

To facilitate your data transition process, we are providing the following conversion formulas:

1. Correlating OLD diluent data to NEW diluent data:

$$(OLD value \times 0.8014) - 0.5736 = NEW value$$

2. Correlating NEW diluent data to OLD diluent data:

(NEW value x 1.22) + 0.956 = OLD value

*Salivary Estradiol Expected Ranges with NEW diluent

Changes to normal ranges should be noted on laboratory reports to notify physicians.

| Pre-menopausal Adult Women | N | Mean (pg/mL) | Standard Deviation (pg/mL) |
|-------------------------------|----|--------------|----------------------------|
| Follicular | 20 | 1.35 | 0.80 |
| Mid-cycle | 19 | 2.97 | 1.58 |
| Luteal | 20 | 2.56 | 0.84 |

^{*}To be used as a guide only. Each laboratory should establish new normal ranges. Any quantitative results indicating abnormal estradiol levels should be evaluated along with patient history, symptoms and other laboratory tests.

Please contact the Salimetrics Technical Service Team with any questions.

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Sincerely, *Technical Support Team*