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To: All Clients

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In a continued effort to provide quality results to our clients and patients, The Pathology Laboratory received notice from Roche, manufacturer of the Estradiol III reagent, that an internal investigation revealed a cross-reactivity between Fulvestrant (Faslodex) and the Estradiol III reagent. Women being treated with Fulvestrant will show an increase in estradiol concentrations being reported with the Estradiol III assay.

If the estradiol status of postmenopausal women under treatment with Fulvestrant is tested with the Estradiol III assay, an interference leading to falsely increased results of estradiol may occur. Subsequently, the incorrect level of estradiol may lead to misinterpretations of the hormone status and the use of Fulvestrant may be altered. In addition, the efficiency of anti-estrogen treatment might be underestimated. A medical risk for postmenopausal women under Fulvestrant cannot be excluded.

If treatment with Fulvestrant has been altered or discontinued as a result of falsely elevated estradiol results, an alternate method such as LC-MS, which is not expected to show cross-reactivity to Fulvestrant, should be used to measure estradiol concentrations and assess the menopausal status of these patients.

If you are treating a patient with Fulvestrant, please order code SPLZ30289, Estradiol, Ultrasensitive, LC/MS/MS.

If you have any questions or concerns, please contact Nicho Bourque, lab manager, at 337-312-1280 at nbourque@thepathlab.com or Diane Buck at 337-312-1295 or dbuck@thepathlab.com.

The Pathology Laboratory appreciates your business and your continued patronage.