Biocept
Completing the Answer™

IMPORTANT NOTICE

IMPROVED CTC SPECIFICITY

Date: June 19, 2020
To: Valued Customer
From: Biocept Customer Service Team
Re: Update to our CTC Capture Specificity and Limit of Detection (LOD)

This notice is to inform you of an update regarding Biocept's circulating (CTC) capture specificity and Limit of Detection (LOD) as a result of our ongoing continuous quality and process improvements process.

Biocept is pleased to inform you that, as part of our technology enhancements, our clinical specificity for CTC capture has increased to 95%. In addition, Biocept now provides LOD for both CTC subpopulations, cytokeratin positive (CK+) and cytokeratin negative (CK-). Our new LOD is 1 CK+ CTC and / or 2 CK- CTCs per 8 mL of blood.

This new process has been validated in alignment with the accreditation requirements of College of Pathology and Biocept's CLIA license.

These new process improvements may result in test results that differ from prior tests for the patients you have been monitoring with CTCs. It is Biocept's recommendation that you consider having your patients obtain another CTC test in the near future to obtain "re-baselined" results. However testing decisions are at the sole discretion of the ordering physician. The intended use of Biocept's tests is adjunctive to clinic-pathological and radiological findings and not for diagnosis or to be used as a sole diagnostic entity.

If you have any questions regarding this new process improvement or its potential impact to results or your patients, Biocept's Customer Service Department and/or Medical Director is happy to respond.

We look forward to continuing to provide you and your patients with state-of-the-art CTC testing.

Kind regards,

Biocept Customer Service