

## Cytogen circulating tumor cell liquid biopsy platform process analytical validation

### Executive Summary:

Cytogen has developed an automated liquid biopsy platform that includes instruments that work in concert to detect the presence of circulating tumor cells (CTCs). The three instruments are –




Patient samples are isolated, stained and analyzed for the presence of CTCs based on the expression of . The goal of this study is to assess the Cytogen’s circulating tumor cell (CTC) liquid biopsy platform, for use at the CLIA laboratory in . To this end, an analytical validation plan was designed to include Analytical accuracy, Precision, Reproducibility, Limit of detection (LOD) experiments. Experiments were carried out as designed.

- Various experiments were carried out analytically validate they Cytogen CTC isolation platform at
- All isolations were carried from blood as the starting sample.
- Experiments included – Accuracy, Precision & LOD.
- Accuracy –
  - included blood from donors, with
  - included blood from donors.
  - samples were negative, had expected staining results.
- Precision –
  - A sample was extracted in from collection for precision.
  - A sample with was extracted, from collection for precision.
  - Precision data for both samples was similar across all
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Based on these results, is analytically validated to perform CTC detection using the Cytogen liquid biopsy platform.

**Signatures:**

The following sign offs indicate that the above-named study has been reviewed and approved.

Author	DocuSigned by:  09-Aug-2021   08:47:32 PDT
Chief Development Officer	DocuSigned by:  09-Aug-2021   08:51:25 PDT
Chief Medical Officer	DocuSigned by:  09-Aug-2021   08:47:29 PDT