SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE RE: DOCUMENT NUMBER K151935

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

   Trade Names: Alere Signify *H. pylori* - Whole Blood, Serum, Plasma
   Alere Signify *H. pylori* - Whole Blood Only
   Alere Clearview *H. pylori* - Whole Blood, Serum, Plasma
   Alere Clearview *H. pylori* - Whole Blood Only

   510(k) number: K024350

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This is a labeling change to remove a limitation for triglycerides as a potentially interfering substance. This labeling change does not affect the intended use or the instructions for use. There were no modifications to the device.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and interfering substances.

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

      Based on the risk analysis, analytical validation was conducted to demonstrate that triglyceride levels up to 3454 mg/dL do not negatively affect device performance with whole blood, serum, or plasma sample types.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.