1. **Is CMS aware of the disruptions in the availability of BD BACTEC™ Blood Culture Media Bottles?**

   The CMS Division of Clinical Improvement and Quality (DCLIQ) is responsible for the oversight of clinical laboratories and laboratory testing. DCLIQ is aware of the BD BACTEC™ blood culture media bottle supply issue and has heard from multiple stakeholders about the disruptions caused by this shortage. CMS remains in close contact with the FDA and other HHS partners to monitor the supply situation.

   Laboratories experiencing disruptions in their supply of BD BATEC blood culture media bottles and health care providers who order blood cultures should consider developing strategies to prioritize the use of blood culture media bottles, based on clinical need, to maintain quality and safety of patient care. Considerations for developing these strategies and links to additional informational resources can be found in the FDA Letter to Health Care Providers.

2. **Can a laboratory use expired BD BACTEC™ Blood Culture Media Bottles during the shortage?**

   The CLIA regulations at 42 C.F.R. § 493.1252(d) state that "[r]eagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality." BD™ has extended the shelf-life for specific lots of BD BACTEC™ Blood Culture Media Vials in the US. Please contact BD™ for additional information. For lots that have not had their shelf-life extended, the use of expired reagents would be considered a test modification and would require the laboratory to establish performance specifications for a modified procedure. [1] In addition, the test would default to high complexity.[2]

3. **BD™ has communicated that they will be launching the BD BACTEC™ Lytic Anaerobic media in glass. What type of verification needs to be performed if my laboratory switches to glass bottles?**

   When the laboratory introduces an unmodified, FDA-cleared or approved test system, it must conduct a verification of performance specification study per § 493.1253(b)(1). CLIA regulations are not prescriptive about the number or type of samples used to perform the verification of performance specification study. The laboratory director is responsible for determining whether the verification of performance specifications study

[1] 42 C.F.R. § 493.1253(b)(2).
[2] 42 C.F.R. § 493.17(c)(4).

meets the regulatory requirements at § 493.1253(b)(1) and which performance characteristics apply (accuracy, precision, reportable range, and reference intervals).

Laboratories should also contact their accrediting organization or state agency as they may have more stringent requirements. More information on the glass bottles and the manufacturer's verification protocol may be found on the BD™ website.