

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1092602	(X3) Date Survey Completed 08/22/2019
Name of Provider or Supplier Cytogenetic Biodosimetry Laboratory/Reacts	Street Address, City, State 1299 Bethel Valley Road Sc-10 Room 107, Oak Ridge, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on August 22, 2019, the laboratory failed to perform competency assessment for 2 out of 2 testing personnel (TP) for 2018. Findings include: Record review on August 22, 2019 at approximately 12:00 PM, revealed the absence of testing personnel competency assessment records for the year of 2018 for TP1 and TP2. Interview with TP1 and the Technical Supervisor on August 22, 2019 at approximately 12:15 PM, revealed that competency assessment for TP1 and TP2 was not performed for the year of 2018.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on August 22, 2019, the laboratory failed to establish and follow a general laboratory systems quality assessment (QA). Findings include: Record review on August 22, 2019 at approximately 12:30 PM of</p>

the "Quality Assurance/Quality Control Requirements Procedure," revealed that the procedure did not include information regarding an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. TP1 and the Technical Supervisor acknowledged in an interview on August 22, 2019 at approximately 12:40 PM, that the laboratory failed to include in the procedure, an ongoing review process that encompassed all facets of the laboratory's technical and non-technical functions.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and staff interview on August 22, 2019, the laboratory failed to document control procedures performed for each batch of media received and used for the testing process. Findings include: Record review on August 22, 2019 at approximately 12:30 PM, revealed that the laboratory failed to document a verification regarding sterility and ability to support growth for the PB-MAX Karotyping Medium. During an interview on August 22, 2019 at approximately 12:35 PM, TP1 and the Technical Supervisor stated that the Certificate of Analysis was being used as verification to support the claims of sterility and ability to support growth for the PB-MAX Karotyping Medium.