

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2210993	(X3) Date Survey Completed 06/17/2022
Name of Provider or Supplier Honeycomb Medical Group,Plc	Street Address, City, State 6401 Poplar Ave, Suite 296, Memphis, 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
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) form, the QC data from the Access 2 instrument, the QC data from the laboratory information system (Medicus) and the reports printed for quality control review, and interview with the laboratory director, the laboratory's quality assessment process was ineffective when it did not include review of all quality control data and failures in May 2022. 1. Review of the laboratory's monthly quality control review form revealed the following "Access 2" box checked, reviewed by technical consultant number one on 06/01/2022, and a box was checked for "No Exceptions Noted, QC O.K." 2. Review of the quality control data from the Access 2 instrument revealed multiple QC failures for Thyroid Stimulating Hormone (TSH) on 05/27/2022. 3. Review of the quality control data in the Medicus laboratory information system (LIS) revealed the presence of the failed quality control values as indicated in the Access 2 instrument. 4. Review of the reports printed for secondary review by the laboratory director revealed the failed quality control values that were in the Access instrument QC files and the Medicus LIS were not included on the reports printed for final QC review. 4. Interview with the laboratory director on 06/17/2022 at 2:00 pm confirmed the laboratory's quality assessment process was ineffective when the reports printed for retrospective review of quality control data did not include the complete history of analyte failures for May 2022 quality control for the TSH analyte.</p>