

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0283906	(X3) Date Survey Completed 01/03/2020
Name of Provider or Supplier Cell Science Systems Corporation	Street Address, City, State 852 S Military Trail, Deerfield Beach, FL	
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
D0000	A recertification survey conducted on 01/03/2020 found that the Cell Science Systems Corporation clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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, the laboratory failed to perform competency assessment for 1 out of 1 clinical consultant (CC) for 2 out of 2 (2018 -2019) years reviewed. Findings include: Review of personnel files revealed that: - There was no documentation of competency assessment for the CC for the years 2018 and 2019. During an interview on 01/03/2020 at 2:30 PM, with testing person (TP) A, she confirmed that there was no documentation of the competency assessment for the CC for the period of reference.</p>
D6144	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation that the General Supervisor (GS) provided day to day supervision of</p>

laboratory operation and personnel performing testing and reporting results. Findings include: -Review of CMS 209 Laboratory Personnel Report signed by the Laboratory Director (LD) and dated on 01/02/2020 revealed: LD as a Technical Supervisor (TS) and GS. -No documentation of the daily review by the GS of laboratory activity found during the visit. During an interview on 01/03/2020 at 2:30 pm with TP # A confirmed that the GS is not daily at the laboratory and no documentation of the daily supervision was provided.