

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2158618	(X3) Date Survey Completed 04/05/2021
Name of Provider or Supplier Dallas Ivf - Bumc	Street Address, City, State 3600 Gaston Ave Suite 1001 Barnett Tower, Dallas, TX	
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	<p>An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, package insert and staff interview, the laboratory failed to ensure 3 of 3 QuickLink staining solutions stored in secondary containers were labeled with identifying lot numbers, storage requirements, poured dates and expiration dates. Findings Included: 1. During a tour of the lab on 04/05/2021 at 12:17</p>

PM, the surveyor observed staining solutions in secondary containers on the laboratory counter. Testing Person #1 was asked what the specific contents of the containers were. Testing Person #1 stated the containers were Quicklink staining solutions. The Quicklink staining solutions (Package insert Rev: 01.31.2020) are as follows: a. Quicklink III Fixative Solution b. Quicklink III Solution I c. Quicklink III Solution II Upon inspection of the containers, it was revealed the laboratory failed to ensure 3 of 3 QuickLink staining solutions stored in secondary containers were labeled with lot numbers, storage requirements, poured dates and expiration dates. 2. During the exit interview on 04/05/2021 at 1:00 PM, in the break room, the laboratory supervisor acknowledged the above findings.