

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0167925	(X3) Date Survey Completed 07/28/2022
Name of Provider or Supplier Women's Ob/Gyn, Pc	Street Address, City, State 401 Main St, 1st Fl, Johnson City, NY	
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
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Control Procedure (QCP) for the Affirm VPN analyzer, Affirm Quality Control (QC) results, and an interview with the laboratory director and testing person, the laboratory failed to follow the written QCP and perform external positive & negative controls to ensure the proper performance of Probe Analysis Card (PAC), Reagent Cassette (RC) and Processor from January 1, 2020 through survey date. FINDINGS: 1. The laboratory is using a positive Trivalent control swab to test the PAC & RC with each new lot and weekly on the Affirm VPN analyzer. a. The QCP states, " that QC is performed using both positive and negative Trivalent control swabs with each new lot of PAC & RC and weekly. b. Approximately 2,091 patient samples were tested and reported during this time period. 2. The laboratory director and testing person confirmed on July 28, 2022 at approximately 2:30 PM, the laboratory failed to follow QCP and perform a external negative control for the PAC & RC performed on the Affirm VPN from January 1, 2020 through survey date.</p>