

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0997083	(X3) Date Survey Completed 08/01/2018
Name of Provider or Supplier Virginia Womens Center	Street Address, City, State 12129 Graham Meadows Drive, Richmond, VA	
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	An announced CLIA recertification survey was conducted at Virginia Women's Center on August 1, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of the Laboratory Personnel Report Form (CMS 209), procedure and policy manual, personnel files, and an interview, the laboratory did not establish and follow a policy for one (1) technical consultant's competency assessment in calendar years 2016, 2017 and up to the date of the survey on August 1, 2018. Findings include: 1. Review of the CMS 209, revealed that Testing Personnel B serves as Technical Consultant (TC). (See Personnel Code Sheet) 2. Review of the laboratory procedure and policy manual revealed no protocol outlining documentation of the competency assessment of the TC. 3. Review of the personnel files revealed that the laboratory director failed to document competency assessments in calendar years 2016, 2017, and year to date 2018 for Testing Personnel B in the role of TC. 4. In an interview with the TC at approximately 12:00 PM, it was confirmed that laboratory did not establish and follow a policy for documenting competency assessment for the duties of the one (1) TC for the timeframe outlined above.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the laboratory's Quality Assurance (QA) policies, Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, monthly QA reports and an interview, the laboratory director failed to: 1. ensure the laboratory followed their written QA policy to perform annual competency assessments for twenty-two (22) of twenty-two (22) testing personnel in 2017 (Cross reference D6021 Part A); 2. ensure the laboratory follow their written policy to perform and document monthly QA reviews for twenty (20) of twenty-four (24) months reviewed (Cross reference D6021 Part B, *REPEAT DEFICIENCY).

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

A. Based on a review of the procedures and policies, personnel records, quality assurance (QA) reports, and an interview, the laboratory did not follow their written QA policy to perform annual competency assessments for twenty-two (22) of twenty-two (22) testing personnel in 2017. Findings include: 1. Review of the laboratory's procedure manual revealed a QA policy for personnel competency assessment. The policy stated: "At least annually, the lab director and/or technical consultant will review the performance of each testing personnel to assure competency and the written review will be filed in the individual's personnel file". 2. Review of the laboratory's personnel files revealed no annual competency assessments for Testing Personnel A through V in calendar year 2017. (See Personnel Code Sheet) 3. Review of the available QA monthly reports revealed no corrective action documented for the lapse in competency assessment documentation during calendar year 2017. 4. In an interview with the technical consultant (TC) at approximately 12:00 PM, it was confirmed that the laboratory had not followed their written QA policy to perform and document testing personnel competency assessments in calendar year 2017. B. Based on a review of the procedures and policies, quality assurance (QA) checklist reports, and an interview, the laboratory did not follow their written policy to perform and document monthly QA reviews for twenty (20) of twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed a QA policy for Quality Assurance Plan. The policy stated: "We will perform quality assurance reviews at least monthly and review results with the lab director and/or technical consultant". 2. Review of the monthly QA checklists for the timeframe of August 2016 through the date of the survey on 8/1/18, revealed four (4) monthly reports were documented (5/2/17, 12/1/17, 3/30/18, 7/3/18). The inspector requested to review additional monthly QA checklists. No other records were available. 3. In an

interview with the TC at approximately 12:00 PM, it was confirmed that the laboratory had not followed their written QA policy to perform monthly quality assurance checklist reviews for twenty (20) of twenty-four (24) months reviewed.
**REPEAT DEFICIENCY

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to assess annual competency for twenty-one (21) of twenty-two (22) testing personnel in 2017. Findings include: 1. Review of the CMS Form 209: Laboratory Personnel Report revealed that there are twenty-two (22) testing personnel and that TP B performs the duties of TC. (See Personnel Code Sheet) 2. Review of the laboratory personnel files revealed no record of annual competency assessments in calendar year 2017 for: Testing personnel A, Testing personnel C, Testing personnel D, Testing personnel E, Testing personnel F, Testing personnel G, Testing personnel H, Testing personnel I, Testing personnel J, Testing personnel K, Testing personnel L, Testing personnel M, Testing personnel N, Testing personnel O, Testing personnel P, Testing personnel Q, Testing personnel R, Testing personnel S, Testing personnel T, Testing personnel U, Testing personnel V. The inspector requested to review the 2017 annual competency documentation. The documentation was not available for review. 3. In an interview with the TC at approximately 12:00 PM, it was confirmed that the laboratory failed to document competency assessments for the twenty-one (21) testing personnel outlined above in calendar year 2017.