

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659873	(X3) Date Survey Completed 05/07/2021
Name of Provider or Supplier Tarrant County Public Health Dept	Street Address, City, State 1101 South Main Street, Fort Worth, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) 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.
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS-209 form signed by the Laboratory Director (LD), testing personnel (TP) initial competency assessments from 2020, competency assessment policy/procedure, and confirmed in an interview revealed the Technical Supervisor (TS) failed to document complete competency assessments for 4 of 13 TP's (TP5, TP9, TP10, and TP11). The findings were: 1. Review of CMS-209 form revealed TP5, TP9, TP10, and TP11 listed for high complexity tests including Hologic Panther APTIMA SARS-CoV-2 Assay. 2. Review of initial competency assessments of Hologic Panther APTIMA SARS-CoV-2 Assay from 2020 for the above TPs failed to include 3 of 6 required competency components as follows: a) Review of intermediate quality control records, proficiency testing results, and preventive maintenance records; b) direct observation of performance of instrument maintenance and function checks; c) assessment of problem solving skills. TP5, hired on 9/28/95 Competency Assessment for Hologic Panther APTIMA SARS-CoV-2 Assay revealed proficiency testing (PT), quality control records reviews, maintenance and function checks, and problem solving skills components documented as Not Applicable (NA), and was signed by TS</p>

on 6/29/20. TP9, hired on 10/15/12 Competency Assessment for Hologic Panther APTIMA SARS-CoV-2 Assay revealed proficiency testing (PT), quality control records reviews, maintenance and function checks, and problem solving skills components documented as Not Applicable (NA), and was signed by TS on 6/29/20. TP10, hired on 6/14/16 Competency Assessment for Hologic Panther APTIMA SARS-CoV-2 Assay revealed proficiency testing (PT), quality control records reviews, maintenance and function checks, and problem solving skills components documented as Not Applicable (NA), and was signed by TS on 6/29/20. TP11, hired on 5/18/16 Competency Assessment for Hologic Panther APTIMA SARS-CoV-2 Assay revealed proficiency testing (PT), quality control records reviews, maintenance and function checks, and problem solving skills components documented as Not Applicable (NA), and was signed by TS on 6/29/20. 3. Review of competency assessment policy /procedure under IX. OBJECTIVE revealed, "To establish a systematic method of assessing competency that includes all elements of a CLIA Competency Assessment program. The following six procedures are the minimal regulatory requirements for assessment for competency for all personnel performing laboratory testing..... Competency assessment, which includes the six procedures above, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform." 4. An interview with the technical supervisor on 5/6/21 at 1430 in the office confirmed all testing personnel (TP) reported patient results.