Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0492538	(X3) Date Survey Completed 06/01/2021
Name of Provider or Supplier Ut Physicians Bay Area Pediatrics	**Street Address, City, State** 17150 El Camino Real, Houston, 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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1421 D6063 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing a competency assessment for 2 of 3 clinical consultants. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 6/1/21) revealed the laboratory identified 2 clinical consultants. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing a competency assessment for: Clinical Consultant #2 Clinical Consultant #3 3. An interview with the laboratory director on 6/1/21 at 10:30 a.m. in exam room 12 revealed the laboratory

	did not assess the competency of the clinical consultants. This confirmed the above findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure that 1 of 4 testing personnel had documentation of training on the Abbott Cell Dyn Emerald hematology analyzer prior to performing patient testing (refer to D6066).
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the education to determine the qualifications of 1 of 4 testing personnel to perform moderate complexity testing (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education for 1 of 4 testing personnel to qualify them to perform moderate complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 6/1/21) revealed 4 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for 1 of 4 testing personnel. The testing person missing the documentation of education: Testing Person #4 (as indicated on the CMS 209 form) 3. The laboratory director was asked to provide the documentation of education. No documentation was provided. 4. An interview with the laboratory director on 6/1/21 at 10:00 a.m. in exam room 12, after review of the records, confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, and staff interview, it was revealed that 1 of 4 testing personnel failed to have documentation of training on the Abbott Cell Dyn Emerald hematology analyzer prior to performing patient testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 6/1 /21) revealed the laboratory identified 4 testing personnel who performed moderate complexity testing on the Abbott Cell Dyn Emerald hematology analyzer. 2. A review of the laboratory's personnel records revealed that testing person #4 did not have documentation of training on the Abbott Cell Dyn Emerald hematology analyzer prior to performing patient testing. 3. Further review of the laboratory's personnel records revealed that testing person #4 was hired in April 2021. 4. An interview with the laboratory director on 6/1/21 at 10:05 a.m. in exam room 12 revealed the laboratory did not have documentation of the training for testing person #4. This confirmed the above findings.