Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D2059795	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Partners 4kids	1 Estate Thomas, St Thomas, VI	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to sign the attestation for six of six proficiency events reviewed. Findings: 1. Review of proficiency testing events 2019-3, 2020-1, 2020-2, 2020-3, 2021-1 and 2021-2 for hematology revealed no laboratory signature on the proficiency testing attestation statement. 2. In interview on September 21, 2021 at approximately 11:57 AM, testing personnel #1 (TP1) confirmed that the laboratory director did not sign the proficiency testing attestation statements.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain instrument printouts from the hematology instrument for three out of four patients reviewed. Findings: 1. Hematology patient test records were reviewed for the following dates: 08/18/2021, 09/08/2020, 01/13/2020, and 01/14/2021. 2. Instrument printouts from the hematology analyzer were only available for the patient tested on 08

	/18/2021. No instrument printouts were available for the patients tested on 09/08 /2020, 01/13/2020, and 01/14/2021. 3. In interview on September 21, 2021 at approximately 11:38 AM, testing personnel #1 (TP1) confirmed that the instrument printouts from the hematology instrument were recently discarded and the instrument was not directly interfaced to the laboratory information system.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain testing records for one of six proficiency testing events reviewed. Findings: 1. Review of proficiency testing events 2019-3, 2020-1, 2020-2, 2020-3, 2021-1 and 2021-2 for hematology revealed no instrument printouts for event 2020-2. 2. In interview on September 21, 2021 at approximately 11:57 AM, testing personnel #1 (TP1) confirmed that there was no documentation of testing records for event 2020-2.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to review and evaluate results obtained for six of six proficiency testing events reviewed. Findings: 1. Review of proficiency testing events 2019-3, 2020-1, 2020-2, 2020-3, 2021-1 and 2021-2 for hematology revealed no evidence of review or evaluation. 2. In interview on September 21, 2021 at approximately 11:57 AM, testing personnel #1 (TP1) confirmed that there was no documentation of review or evaluation for the six proficiency testing events.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to ensure external quality control was used to monitor the analytic testing system for one of one instrument in use. (See D5447)
D5447	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to run two levels of external quality control each day of patient testing for one of one instrument in use. Findings: 1. Review of procedure "Calibration and Quality Control" under section "External liquid controls" stated "You must run liquid controls and document the results before you begin testing with a new lot or newly received shipment of QBC STAR Tubes. You must run liquid controls and document the results with each instance of instrument relocation or repair. Consult the package insert accompanying the controls for preparation instructions and expected results. You must also follow any quality control requirements from your regulatory or accreditation agencies." 2. In interview on September 21, 2021 at approximately 09: 15 AM, testing personnel #1 and testing personnel #2 stated that there were no external quality control records for the hematology analyzer. 3. In interview on September 21, 2021 at approximately 09:30 AM, the laboratory director stated that no external quality control was available and that the company no longer manufacturers the quality control. 4. No documentation of an Individualized Quality Control Plan or alternative control procedures were found during the survey.
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 record review, lack of documentation, and interview, the laboratory director failed to document training on the hematology analyzer prior to patient testing for one of two testing personnel. Findings: 1. Review of procedure "Personnel Training and Qualifications" under section "Laboratory Personnel" stated "It is imperative that training is documented for the tests that personnel are authorized to perform." 2. In interview on September 21, 2021 at approximately 11:30 AM, testing personnel #2 (TP2) confirmed she was hired in June 2020. 3. Review of TP2 employee records revealed no training on the hematology analyzer in 2020. 4. In interview on September 21, 2021 at approximately 11:30 AM, testing personnel #1 (TP1) and TP2 confirmed no records of training for TP2 were available for 2020.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the technical consultant failed to document semiannual competency during the first year the individual performed hematology testing for one of two testing personnel. Findings: 1. Review of procedure "Personnel Training and Qualifications" under section "Personnel Evaluation" stated "Personnel must be evaluated by the technical consultant at least semiannually during the first year of employment." 2. In interview on September 21, 2021 at approximately 11:30 AM, testing personnel #2 (TP2) confirmed she was hired in June 2020. 3. Review of TP2 employee records revealed no semiannual competency on the hematology analyzer. 4. In interview on September 21, 2021 at approximately 11:30 AM, testing personnel #1 (TP1) and TP2 confirmed semiannual competency was not available for TP2 for the first year of patient testing.
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 record review, lack of documentation, and interview, the laboratory failed to have documentation of qualifications for one of two testing personnel. (See 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 record review, lack of documentation, and interview, the laboratory failed to have documentation of qualifications for one of two testing personnel. Findings: 1. Review of testing personnel #1 (TP1) employee records revealed no documentation of qualifications for moderately complex testing. 2. In interview on September 21, 2021

	at approximately 11:30 AM, testing personnel #1 (TP1) confirmed there was no documentation.