Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0722545	01/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Babies & Childrens Clinic	900 West Sam Houston Suite 1, Pharr, 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 representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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 certification is recommended. 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the EUA for the Quidel QuickVue SARS Antigen Test, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of training testing personnel. The findings include: 1. A review of the EUA for the Quidel QuickVue SARS Antigen Test (1461800 12/20) under the section titled "Intended Use" revealed: "The QuickVue SARS Antigen test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings." 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of training 6 of 6 testing personnel on the Quidel QuickVue SARS Antigen test. 3. An interview with testing personnel number 2 (as

	listed on Form CMS 209) on 01/27/2022 at 1000 hours in the COVID testing area - after her review of the records- confirmed the findings.
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 review of the laboratory's American Academy of Family Physicians proficiency testing records from 2021 and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 2 of 3 attestation statements. The findings include: 1. A review of the laboratory's American Academy of Family Physicians proficiency testing records from 2021 (events 1, 2 and 3) revealed the laboratory failed to have documentation of the laboratory director signing 2 of 3 attestation statements. The statements without laboratory director signatures were: 2021 event 1 2021 event 3 2. The laboratory was asked to provide documentation of the laboratory director signing the identified attestation statements. No documentation was provided. 3. An interview with testing personnel number 2 (as listed on Form CMS 209) on 01/27/2022 at 945 hours in the COVID testing area - after her review of the records- confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Medonic M-series hematology analyzer, review of the laboratory's maintenance records from 2020 and 2021, and staff interview, it was revealed the laboratory failed to have documention of performing maintenance as required. The findings include: 1. A review of the manufacturer's instruction for the Medonic M-series hematology analyzer (PN207057B R05.03.16) revealed the following maintenance was required monthly and every six months: a) Monthly Monthly Cleaning Clot Prevention b) Six Month Six month maintenance 2. A review of the laboratory's Medonic M-series maintenance records from 2020 and 2021 identified the laboratory failed to have documentation of the following: a) Monthly - Clot prevention (21 of 24 months) January 2020 March 2020 April 2020 May 2020 June 2020 July 2020 August 2020 September 2020 October 2020 November 2020 January 2021 March 2021 April 2021 May 2021 June 2021 July 2021 August 2021 September 2021 October 2021 November 2021 December 2021 b) Six month maintenance August 2020 August 2021 2. The laboratory was asked to provide documentation of performing the required maintenance. No documentation was provided. 3. An interview with the testing personnel number 2 (as listed on Form CMS 209) on 01/27/2022 at 1030 hours - after her review of the records- confirmed the findings.

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology quality control records from August 2021, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when quality control failed. The findings include: 1. A review the laboratory's hematology quality control records from August 2021 revealed that on August 29, 2021 two levels of quality control failed to fall within the acceptable range for MCV (mean corpuscular volume). They were: Level 1 Level 3 A handwritten note by the technical consultant on the page stated: "Two controls were out. Clinic will follow up with the patients that were run on this date" signed by the technical consultant on 09/21/2021. 2. The laboratory was asked to provide documentation of performing corrective actions or of following up on the patients tested that day. No documentation was provided. 3. A review of patient test records identified 15 patients who were tested that day. (see patient alias list). 4. An interview with testing personnel number 2 (as listed on Form CMS 209) on 01/27/2022 at 1100 hours in the hallway - after her review of the records - confirmed the findings.