Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0995218	01/31/2020
Name of Provider or Supplier	**Street Address, City, State**	
G Athanasi Orfanos Md Pediatrics	2703 W Trenton, Edinburg, 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 at the entrance and exit conferences. The facility representative was 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. 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of manufacturer's instructions, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of following its CBC repeat policy. The findings were: 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" stated, "It will be the policy of this laboratory to return (sic) flagged CBC results. If the second run still shows flags, then lab will evaluate flagged differentials according the procedures in the unit's operator manual. See that the sample requirements are met, that the unit is in good working order, and that the

	testing procedure is correctly followed. Sometimes the flags will disappear when the sample is allowed to equilibrate at room temperature for 15-20 minutes, or by redrawing the patient. If the flags disappear, then report the result." 2. A review of the manufacturer's instructions for the Medonic hematology analyzer (SN 26075 Article no: 1504283 November 2012) under the section titled "9.2 System Messages" under "Abnormalities" stated "Follow your laboratory's protocol for verification on all samples with anomalies and/or abnormal distributions signaled by the instrument. Pathological cells may vary in their stability towards lysing of their cytoplasmic membranes compared to normal cell., which may cause aberration in the automated analysis ...." BD - WBC Diff: High interference between population Action: blood sample too old or pathological sample. follow laboratory's protocol for verification of results. OM - WBC Diff: Only once WBC population found; slide review advised Action: blood sample too old or pathological sample. follow laboratory's protocol for verification of results. 3. Review of patient records from July 1, 2019 to September 30, 2019 identified the following 47 of 83 of patient CBC tests that did not have documentation of repeat analysis prior to releasing results to the healthcare provider. No documentation of repeat CBC Date tested Patient Seq # 3257 07/16/19 @ 17:46 * Patient Seq # 3296 07/18/19 @ 19:14 * Patient Seq # 3323 07/20/19 @ 20:26 * Patient Seq # 3333 07/21/19 @ 17:23 * Patient Seq # 3334 07/21/19 @ 19:40 * Patient Seq # 3348 07/22/19 @ 12:52 * Patient Seq # 3350 07/22/19 @ 15:29 * Patient Seq # 3391 07/24/19 @ 18:56 * Patient Seq # 3393 07/24/19 @ 19:54 * Patient Seq # 3407 07/25/19 @ 14:49 * Patient Seq # 3409 07/25/19 @ 15:16 * Patient Seq # 3514 07/31/19 @ 18:00 * Patient Seq # 3490 07/30/19 @ 16:49 * Patient Seq # 3560 08/03/19 @ 11:14 * Patient Seq # 3584 08/05/19 @ 13:22 * Patient Seq # 3614 08/06/19 @ 09:24 * Patient Seq # 3621 08/06/19 @ 16:31 * Patient Seq # 3654 08/07/19 @ 18:13 * Patient Seq # 3689 08/09/19 @ 17:41 * Patient Seq # 3702 08/10/19 @ 20:33 * Patient Seq # 3818 08/15/19 @ 18:46 * Patient Seq # 3848 08/16/19 @ 22:25 * Patient Seq # 3889 08/19/19 @ 10:47 * Patient Seq # 3959 08/21/19 @ 11:10 * Patient Seq # 3966 08/21/19 @ 15:38 * Patient Seq # 4016 08/24/19 @ 11:57 * Patient Seq # 4038 08/26/19 @ 09:21 * Patient Seq # 4043 08/26/19 @ 15:53 * Patient Seq # 4046 08/26/19 @ 17:19 * Patient Seq # 4071 08/27/19 @ 20:15 * Patient Seq # 4152 08/31/19 @ 19:17 * Patient Seq # 4226 09/06/19 @ 13:11 * Patient Seq # 4280 09/09/19 @ 15:22 * Patient Seq # 4362 09/12/19 @ 13:37 * Patient Seq # 4369 09/12/19 @ 18:12 * Patient Seq # 4370 09/12/19 @ 18:28 * Patient Seq # 4371 09/12/19 @ 18:48 * Patient Seq # 4430 09/16/19 @ 09:27 * Patient Seq # 4433 09/16/19 @ 10:34 * Patient Seq # 4464 09/17/19 @ 16:29 * Patient Seq # 4499 09/19/19 @ 13:45 * Patient Seq # 4543 09/19/19 @ 13:23 * Patient Seq # 4557 09/20/19 @ 10:35 * Patient Seq # 4605 09/23/19 @ 12:30 * Patient Seq # 4627 09/24/19 @ 12:58 * Patient Seq # 4628 09/24/19 @ 13:01 * Patient Seq # 4644 09/24/19 @ 11:25 * Note: According to the patient data summary the asterisk denotes the specimen has flags. 4. An interview with testing person #1 (as listed on Form CMS-209) on 01/31/2019 at 10:49 hours in the laboratory, after her review of the records- confirmed the findings. Key BD - WBC Diff: High interference between populations OM - WBC Diff: Only one WBC population found; slide review advised CBC - Complete blood count CMS - Centers for Medicare and Medicaid Services SEQ - Sequence
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions, review of patient test records, and staff interview, the laboratory failed to ensure CBC (complete blood count) results with flags were resolved prior to their release to the provider. 1. Review of the laboratory policy "Policy for abnormal Differentials" approved by the laboratory director 01/26/2012, stated "It will be the policy of this laboratory to send out abnormal differentials to the laboratory Directors (sic) discretion. The Laboratory Director will determine if an abnormal differential is required post evaluating CBC results and assessing patient findings. If your CBC instrumentation is showing alarms (R1, R2, M# etc.) in the differential section of the report, it will be considered an abnormal differential and the Laboratory Director must be notified for further instruction." Note: This policy refers to the facility's previous analyzer. 2. A review of the manufacturer's instructions for the Medonic hematology analyzer (SN 26075 Article no: 1504283 November 2012) under the section titled "9.2 System Messages" under "Abnormalities" stated "Follow your laboratory's protocol for verification on all samples with anomalies and/or abnormal distributions signaled by the instrument. Pathological cells may vary in their stability towards lysing of their cytoplasmic membranes compared to normal cell., which may cause aberration in the automated analysis ...." BD - WBC Diff: High interference between population Action: blood sample too old or pathological sample. follow laboratory's protocol for verification of results. OM - WBC Diff: Only once WBC population found; slide review advised Action: blood sample too old or pathological sample. follow laboratory's protocol for verification of results." 3. Review of random patient test records from December 10, 2019 - December 12, 2019 revealed 5 of 8 patients with flags did not have verification of the flags. Seq # Date 6216 12/10/2019 Flag: OM 6306 12/14/2019 Flag: BD 6387 12/19/2019 Flag: OM 6403 12/20/2019 Flag: BD 6458 12/23/2019 Flag: BD The laboratory's policy failed to ensure abnormal flags on CBC tests were verified prior to their release to the healthcare provider. 5. A review of CMS 116 signed by the laboratory director 01/31/2020, revealed the laboratory performed 21600 hematology tests annually. 6. An interview with testing personnel #1 (as listed on form CMS 209) 01/31/2020 at 11:00 hours in the office area confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services Seq - Sequence
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken

when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, review of the laboratory's environmental monitoring records from January 1, 2019 to December 31, 2019, and confirmed in interview with facility personnel, it was revealed the laboratory failed to have documentation of corrective action when it failed to document the laboratory's room temperature and humidity on patient testing days. The findings were: 1. A review of the laboratory policy titled "Instrument Operation and Maintenance" (approved by the laboratory director 1/4/11) states, "Temperature readings of temperature control devices will be made daily and documented." 2. A review of the laboratory's environmental records from January 1, 2019 through December 31, 2019 revealed the laboratory failed to have documentation of corrective action for the following 44 days when patients were tested, and the laboratory failed to document the laboratory's room temperature. January 6 January 13 January 20 January 27 February 3 February 10 February 17 February 24 March 3 March 10 March 17 March 24 March 31 April 7 April 14 April 21 April 28 May 5 May 12 May 19 May 26 June 2 June 9 June 16 June 23 June 30 July 7 July 14 July 20 July 21 July 27 July 28 July 29 July 30 July 31 August 4 August 11 August 18 August 25 September 1 September 8 September 15 September 22 September 29 3. A review of the laboratory's environmental records from January 1, 2019 through December 31, 2019 revealed the laboratory failed to have documentation of corrective action for the following 41 days when the laboratory failed to document the laboratory's room humidity on patient testing days. January 6 January 13 January 20 January 27 February 3 February 10 February 17 February 24 March 3 March 10 March 17 March 24 March 31 April 7 April 14 April 21 April 28 May 5 May 12 May 19 May 26 June 2 June 9 June 16 June 23 June 30 July 7 July 14 July 20 July 21 July 27 July 28 August 4 August 11 August 18 August 25 September 1 September 8 September 15 September 22 September 29 4. A random review of patient test records from January 1, 2019 through December 31, 2019 found the following patients tested on days when the laboratory failed to monitor the room temperature of the laboratory. Seq# Date Tested 3213 07/14/19 @ 16:57 3322 07/20 /19 @ 20:17 3333 07/21/19 @ 17:23 3475 07/29/19 @ 18:55 3485 07/30/19 @ 09:48 3502 07/31/19 @ 09:14 3568 08/04/19 @ 17:49 3710 08/11/19 @ 19:42 3878 08/18 /19 @ 18:11 4025 08/25/19 @ 17:27 4159 09/01/19 @ 19:32 4262 09/08/19 @ 17:16 4420 09/15/19 @ 19:01 4585 09/22/19 @ 17::09 4732 09/29/19 @ 17:07 5. A random review of patient test records from January 1, 2019 through December 31, 2019 found the following patients tested on days when the laboratory failed to monitor the humidity of the laboratory. Seq# Date tested 3213 07/14/19 @ 16:57 3322 07/20/19 @ 20:17 3333 07/21/19 @ 17:23 3568 08/04/19 @ 17:49 3710 08/11/19 @ 19:42 3878 08/18/19 @ 18:11 4025 08/25/19 @ 17:27 4159 09/01/19 @ 19:32 4262 09/08 /19 @ 17:16 4420 09/15/19 @ 19:01 4585 09/22/19 @ 17::09 4732 09/29/19 @ 17:07 6. Review of the CMS 116 signed by the laboratory director 01/31/2020 revealed the laboratory performs 21600 hematology tests annually. 7. An interview with testing person number 1 (as listed on Form CMS 209) on 1/31/2020 at 11:30 hours in the office revealed the facility did not document corrective action for not monitoring room temperature and humidity when testing patients. Key Seq - Sequence CMS - Centers for Medicare and Medicaid Services