Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1000973	**(X3) Date Survey Completed** 01/19/2021
Name of Provider or Supplier Family Medicine Clinic Pa	**Street Address, City, State** 704 E Wonsley Drive, Suite 100, Austin, 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	Based on a proficiency testing desk review survey performed on January 19, 2021, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D2017 - 42 C.F.R. 493.807 Condition: Reinstatement of laboratories performing non-waived testing D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency

	Institute proficiency testing records, the facility failed to achieve successful performance in three of three consecutive testing events for the analyte White Blood Cell Differential (WBC Diff), resulting in unsuccessful performance in the specialty of Hematology. Refer to D2121 and D2130.
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b) (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the facility failed to achieve successful performance in three of three consecutive testing events for the analyte White Blood Cell Differential, resulting in a non-initial proficiency testing failure in the specialty of Hematology. Findings include: 1. The laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for the analyte White Blood Cell Differential in the specialty of Hematology: 2019 API 3rd event 30% 2020 API 1st event 0% 2020 API 2nd event 53% 2. The three consecutive failures result in a second unsuccessful performance for the analyte White Blood Cell Differential.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the facility failed to attain a score of at least 80 percent for the analyte White Blood Cell Differential (WBC diff) in three consecutive testing events in 2019 and 2020. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for the analyte White Blood Cell Differential in the specialty of Hematology in three consecutive events: 2019 API 3rd event 30% 2020 API 1st event 0% 2020 API 2nd event 53% 2. Review of the API

	Comparative Evaluation for the 2019 3rd Hematology testing event found the laboratory submitted unacceptable responses for Lymphocytes and Neut/Gran (Neutrophils/Granulocytes), comprising the WBC Diff. a. Review of the results for Lymphocytes % found the laboratory failed to obtain acceptable results in four of five specimens tested as follows: Specimen HSY-11 - The facility reported a value of 33.6%, with an expected result of 24.2 - 32.9%. Specimen HSY-12 -The facility reported a value of 27.4%, with an expected result of 17.8 - 27.2%. Specimen HSY-14 -The facility reported a value of 40.3%, with an expected result of 33.0 - 40.2%. Specimen HSY-15 -The facility reported a value of 34.2%, with an expected result of 24.5 - 33.5%. b. Review of Neut/Gran (Neutrophils/Granulocytes) % found the laboratory failed to submit acceptable responses for 3 of 5 samples tested as follows: Specimen HSY-11- The facility reported a value of 59.5 %, with an expected result of 60.7 - 69.9%. Specimen HSY-14-The facility reported a value of 51.6%, with an expected result of 51.8 - 59.8%. Specimen HSY-15 -The facility reported a value of 59.8%, with an expected result of range 59.9 - 70.0%. 3. Review of the API Comparative Evaluation for the 2020 Hematology 1st testing event found the laboratory submitted unacceptable responses for Lymphocytes and Neut/Gran (Neutrophils/Granulocytes), comprising the WBC Diff. a. Review of the Lymphocytes % results found the laboratory failed to submit acceptable responses for 5 of 5 samples tested as follows: Specimen HSY-01-The facility reported a value of 38.6%, with an expected result of 28.8 - 37.6%. Specimen HSY-02 -The facility reported a value of 31.4%, with an expected result of 21.1 - 30.6%. Specimen HSY-03- The facility reported a value of 26.3%, with an expected result of 13.9 - 23.6% Specimen HSY-04 -The facility reported a value of 39.6%, with an expected result of 29.4 - 38.6% Specimen HSY-05 -The facility reported a value of 33.3%, with an expected result of 20.0 - 29.9%. b. Review of Neut/Gran (Neutrophils/Granulocytes) % results found the laboratory failed to submit acceptable responses for 5 out of 5 samples tested as follows: Specimen HSY-01 - The facility reported a value of 50.8%, with an expected result of 54.5 - 63.4% Specimen HSY-02 -The facility reported a value of 60.1%, with an expected result of 62.3 - 72.3%. Specimen HSY-03 -The facility reported a value of 66.8%, with an expected result of 69.9 - 81.2% Specimen HSY-04 -The facility reported a value of 50.3%, with an expected result of 53.4 - 62.9% Specimen HSY-05 -The facility reported a value of 59.3%, with an expected result of 63.6 - 73.9%. 4. Review of the API Comparative Evaluation for the 2020 Hematology 2nd testing event found the laboratory submitted unacceptable responses for Lymphocytes and Neut/Gran (Neutrophils/Granulocytes), comprising the WBC Diff. a. Review of the Lymphocytes % results found the laboratory failed to submit acceptable responses for 2 of 5 samples tested as follows: Specimen HSY-07 -The facility reported a value of 27.1%, with an expected result of 11.6 - 23.1% Specimen HSY-10 - The facility reported a value of 32.3%, with an expected result of 16.6 - 28.6% b. Review of the Monocytes % results found the laboratory failed to submit acceptable responses for 2 of 5 samples tested as follows: Specimen HSY-07 -The facility reported a value of 15.7%, with an expected result of 3.4 - 7.4% Specimen HSY-10 -The facility reported a value of 12.7%, with an expected result of 4.5 - 8.2% c. Review of the Neut/Grans % results found the laboratory failed to submit acceptable responses for 3 of 5 samples tested as follows: Specimen HSY-07 -The facility reported a value of 57.2 %, with an expected result of 70.4 - 84.2 Specimen HSY-08 -The facility reported a value of 52.1 %, with an expected result of 52.4 - 65.5 Specimen HSY-10- The facility reported a value of 55.0%, with an expected result of 64.3 - 77.9
D2130	HEMATOLOGY CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
I. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and the American Proficiency Institute (API) Comparative Evaluations, the facility failed to achieve satisfactory performance for the same analyte in three consecutive events the analyte White Blood Cell Differential (WBC diff) in 2019 and 2020. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, the laboratory received the following unsatisfactory scores (satisfactory is 80% or greater) for the analyte White Blood Cell Differential in the specialty of Hematology in three consecutive events: 2019 API 3rd event 30% 2020 API 1st event 0% 2020 API 2nd event 53% 2. Review of the API Comparative Evaluation for the 2019 3rd Hematology testing event found the laboratory submitted unacceptable responses for Lymphocytes and Neut/Gran (Neutrophils/Granulocytes), comprising the WBC Diff. a. Review of the results for Lymphocytes % found the laboratory failed to obtain acceptable results in four of five specimens tested as follows: Specimen HSY-11 -The facility reported a value of 33.6%, with an expected result of 24.2 - 32.9%. Specimen HSY-12 -The facility reported a value of 27.4%, with an expected result of 17.8 - 27.2%. Specimen HSY-14 -The facility reported a value of 40.3%, with an expected result of 33.0 - 40.2%. Specimen HSY-15 -The facility reported a value of 34.2%, with an expected result of 24.5 - 33.5%. b. Review of Neut/Gran (Neutrophils/Granulocytes) % found the laboratory failed to submit acceptable responses for 3 of 5 samples tested as follows: Specimen HSY-11 -The facility reported a value of 59.5 %, with an expected result of 60.7 - 69.9%. Specimen HSY-14 -The facility reported a value of 51.6%, with an expected result of 51.8 - 59.8%. Specimen HSY-15 -The facility reported a value of 59.8%, with an expected result of range 59.9 - 70.0%. 3. Review of the API Comparative Evaluation for the 2020 Hematology 1st testing event found the laboratory submitted unacceptable responses for Lymphocytes and Neut/Gran (Neutrophils/Granulocytes), comprising the WBC Diff. a. Review of the Lymphocytes % results found the laboratory failed to submit acceptable responses for 5 of 5 samples tested as follows: Specimen HSY-01 -The facility reported a value of 38.6%, with an expected result of 28.8 - 37.6%. Specimen HSY-02 -The facility reported a value of 31.4%, with an expected result of 21.1 - 30.6%. Specimen HSY-03 -The facility reported a value of 26.3%, with an expected result of 13.9 - 23.6% Specimen HSY-04 -The facility reported a value of 39.6%, with an expected result of 29.4 - 38.6% Specimen HSY-05 -The facility reported a value of 33.3%, with an expected result of 20.0 - 29.9%. b. Review of Neut/Gran (Neutrophils/Granulocytes) % results found the laboratory failed to submit acceptable responses for 5 out of 5 samples tested as follows: Specimen HSY-01 -The facility reported a value of 50.8%, with an expected result of 54.5 - 63.4% Specimen HSY-02 -The facility reported a value of 60.1%, with an expected result of 62.3 - 72.3%. Specimen HSY-03 -The facility reported a value of 66.8%, with an expected result of 69.9 - 81.2% Specimen HSY-04 -The facility reported a value of 50.3%, with an expected result of 53.4 - 62.9% Specimen HSY-05 -The facility reported a value of 59.3%, with an expected result of 63.6 - 73.9%. 4. Review of the API Comparative Evaluation for the 2020 Hematology 2nd testing event found the laboratory submitted unacceptable responses for Lymphocytes and Neut/Gran (Neutrophils/Granulocytes), comprising the WBC Diff. a. Review of the Lymphocytes % results found the laboratory failed to submit

	acceptable responses for 2 of 5 samples tested as follows: Specimen HSY-07 -The facility reported a value of 27.1%, with an expected result of 11.6 - 23.1% Specimen HSY-10 -The facility reported a value of 32.3%, with an expected result of 16.6 - 28.6% b. Review of the Monocytes % results found the laboratory failed to submit acceptable responses for 2 of 5 samples tested as follows: Specimen HSY-07 -The facility reported a value of 15.7%, with an expected result of 3.4 - 7.4% Specimen HSY-10 -The facility reported a value of 12.7%, with an expected result of 4.5 - 8.2% c. Review of the Neut/Grans % results found the laboratory failed to submit acceptable responses for 3 of 5 samples tested as follows: Specimen HSY-07 -The facility reported a value of 57.2 %, with an expected result of 70.4 - 84.2 Specimen HSY-08 -The facility reported a value of 52.1 %, with an expected result of 52.4 - 65.5 Specimen HSY-10 - The facility reported a value of 55.0%, with an expected result of 64.3 - 77.9
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute proficiency testing records quality control records, temperature records, maintenance records, and quality assessment records, the laboratory director failed to provide overall management and direction of the laboratory services. The findings included: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analytes White Blood Cell Differential. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for analyte White Blood Cell Differential (WBC Diff). Refer to D2016 and D2017.