Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1000973	**(X3) Date Survey Completed** 06/22/2020
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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, API (American Proficiency Institute). The facility was found to be out of compliance with the conditions of the CLIA program. The conditions not met were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation in a proficiency testing program
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 desk review of the CASPER Report 155 Individual Laboratory Profile and proficiency testing records, the facility failed to achieve successful performance in

	two of three consecutive testing events for the analyte White Blood Cell Differential, resulting in unsuccessful performance in the specialty of Hematology. (refer to D2130 and D2121 I)
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: I. Based on review of the CASPER Report 155 Individual Laboratory Profile and the API (American Proficiency Institute) Comparative Evaluations, the facility failed to attain a score of at least 80 percent for the analyte White Blood Cell Differential (WBC diff) in two of four testing events in 2019 and 2020. The findings included: 1. Review of the CASPER Report 155 Individual Laboratory Profile found the laboratory received a score of 30% in the 2019 third testing event, and a score of 0% in the first testing event of 2020 for WBC Diff. 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%. II. Based on review of the Casper Report 155 Individual Laboratory Profile and API Comparative Evaluation, the facility failed to

	attain a score of at least 80 percent in the 2020 Hematology 1st testing event for White Blood Cell (WBC) Count. 1. Review of the Casper Report 155 Individual Laboratory Profile showed a score of 40% in the 1st Hematology testing event of 2020 for WBC. 2. Review of the API Comparative Evaluation 1st Hematology event of 2020 showed failures in White [Blood] Cell Count for 3 out of 5 samples tested as follows: Specimen HSY-01 The facility reported a value of 18.5% with an expected result of 13.4 - 18.3% Specimen HSY-04 The facility reported a value of 13.0%, with an expected result of 9.2 - 12.5%. Specimen HSY-05 The facility reported a value of 8.2%, with an expected result of 5.9 - 8.1%.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the Casper Report 155 Individual Laboratory Profile and API (American Proficiency Institute) Comparative Evaluation, the facility failed to attain an overall testing event score of at least 80 percent in the first Hematology testing event of 2020. The findings included: 1. Review of the Casper Report 155 Individual Laboratory Profile showed an overall test event score of 70% in the 1st testing event of 2020 for the specialty of Hematology. 2. Review of the API Performance Summary for the 1st Hematology testing event of 2020 showed scores for individual analytes as follows: White Blood Cell Differential was 0% Erythrocyte Count (RBC) was 100%, Hematocrit was 80% Hemoglobin was 100% Leukocyte Count (WBC) was 40%, and Platelet Count was 100%. The average of these scores is 70%.
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: Based on review of the Casper Report 155 Individual Laboratory Profile and the API (American Proficiency Institute) Comparative Evaluations, the facility failed to achieve satisfactory performance for the White Blood Cell Differential (WBC diff) in 2 of 3 consecutive testing events. The findings included: 1. Review of the of the Casper Report 155 Individual Laboratory Profile showed a score of 30% for WBC Diff in the 3rd Hematology testing event of 2019, and a score of 0% in the 1st Hematology testing event of 2020. 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% and 33.3 for 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%.
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 review of the Casper Report 155 Individual Laboratory Profile and the API (American Proficiency Institute) Comparative Evaluations, the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2016, D2121, D2122 and D2130.