Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2169906	01/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Anupam Md Pa Dba Nag Clinics	4002 Burke Rd Suite A, Pasadena, 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 national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of participation of the CLIA program The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
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 a review of the CMS (Center for Medicare Services) national database and a

	proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2021, it was determined the laboratory has not successfully participated in a proficiency testing program, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of chemistry for the analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); TOTAL CREATINE; GLUCOSE; K (potassium); NA (Sodium); TOTAL PROTEIN (Refer to D2096, D2097)
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2021, it was revealed the laboratory failed to participate in the 3rd chemistry testing event of 2021. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "0" in the 2021 CAP testing event 3 for the following fifteen analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); TOTAL CREATINE; GLUCOSE; K (potassium); NA (Sodium); TOTAL PROTEIN, Triglycerides; HDL; Cholesterol; Amylase. 2. A proficiency desk review of the CAP proficiency testing records from 2021 confirmed that the laboratory failed to participate in CAP Chemistry testing event 3. The PT summary was rated by the provider as unsatisfactory performance for all analytes for the test event.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2021, it was revealed the laboratory failed to achieve satisfactory performance (80% or greater) for the following twelve analytes in two of two consecutive testing events: ALT (alanine aminotransferase); ALBUMIN; ALP

	(Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); TOTAL CREATINE; GLUCOSE; K (potassium); NA (Sodium); TOTAL PROTEIN. Two out of two consecutive unsatisfactory scores results in unsuccessful PT performance. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "60" for the analytes in 2021 CAP testing event 2 and a "0" for CAP testing event 3 for the following twelve analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); TOTAL CREATINE; GLUCOSE; K (potassium); NA (Sodium); TOTAL PROTEIN 2. A proficiency desk review of the CAP proficiency testing records from 2021 confirmed that the laboratory received a chemistry score of 60% for CAP testing event #2 and a "0" for CAP testing event 3 for the following twelve analytes: ALT (alanine aminotransferase); ALBUMIN; ALP (Alkaline phosphatase); AST (aspartate aminotransferase); TBILI (total Bilirubin); CA (Calcium); CL (Chloride); TOTAL CREATINE; GLUCOSE; K (potassium); NA (Sodium); TOTAL PROTEIN
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the CMS (Center for Medicare Services) national database and a proficiency desk review of the College of American Pathologists (CAP) proficiency testing records from 2021, it was revealed the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for two of two consecutive testing events for the specialty of chemistry. Two out of two overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings were: 1. A review of the CMS national proficiency testing database revealed a score of "70" for the 2021 CAP Chemistry 2nd event and "0" for the 2021 CAP Chemistry 3rd event. 2. A proficiency desk review of the CAP proficiency testing records from 201 confirmed that the laboratory received a"70" for the 2021 CAP Chemistry 2nd event and "0" for the 2021 CAP Chemistry 3rd event.
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 a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Findings were: 1. A review of the laboratory proficiency testing results revealed that the laboratory director failed to ensure that the laboratory participated successfully. (refer to D6016) By not providing overall management and direction of the laboratory, the laboratory director could not ensure the accuracy or reliability of all laboratory services provided by the facility.

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 a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an approved proficiency testing program. (refer to D2096, D2097)