Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0721755	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Skippack Medical Lab, Llc	200 Rittenhouse Circle East, Suite 9, Bristol, PA	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records, patient test reports and interview with the laboratory director (LD) and testing personnel # 2 (TP), the laboratory failed to examine 6 of 6 AAB PT hematology testing events in the same manner as patient specimens from 01/01/2021 to the date of survey. Findings include: 1. On the day of survey, 04/13/2023 at 01:30 pm , review of the patient test reports and AAB PT records revealed that the laboratory failed to examine 6 of 6 AAB PT hematology testing events for white blood cell count (WBC) differentials in the same manner as patient specimens from 01 /01/2021 to 04/13/2023. 2. Review of patient test reports revealed the laboratory reported the following WBC differential results: - Neutrophils - Lymphocytes - Monocytes - Eosinophils - Basophils 3. AAB PT records showed the laboratory reported the following for WBC differential results: - Neutrophils - Lymphocytes - Md /Mid/Mixed/Monocyte/Other %- Module A 4. The LD and TP #2 confirmed the finding above on 4/13/2023 around 03:00 pm.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)

	(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with testing personnel #2 (TP), the laboratory failed to provide 1 of 1 attestation statements for chemistry, hematology, and microbiology testing events performed in 2023. Findings Include: 1. On the day of the survey, 04/13 /2023 at 10:30 am, the laboratory could not provide documentation for 1 of 1 AAB PT attestation statements for chemistry, hematology, and microbiology testing for event #1 in 2023. 2. TP #2 confirmed the findings above on 04/13/2023 around 03:00 pm.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's quality control, proficiency testing and patient test report records, and interview with the laboratory director (LD) and testing personnel #2 (TP), the laboratory failed to meet the requirements specified in 493.126, 493.1291, 493.801. Findings include: 1. Failure to perform and document quality control for 3 of 3 automated white blood cell differential analytes performed on the Cell Dyn 1600. See D5441 2. Failure to include the name and address of the laboratory location where the erythrocyte sedimentation rate examinations were performed. See D5805. 3. Failure to test hematology proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. See D2006
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's competency assessment records and interview with the laboratory director (LD), the laboratory failed to establish a competency

	assessment procedure to assess the competency of 2 of 3 technical consultants (TC), 2 of 3 technical supervisors (TS), and 2 of 3 general supervisors (GS) for their supervisory responsibilities in 2021 and 2022. Findings include: 1. On the day of survey, 04/13/2023 at 10:45 am, the laboratory could not provide a competency assessment policy to assess the competency of the following personnel for their supervisory responsibilities in 2021 and 2022: - 2 of 3 TC (on CMS 209, personnel #2 and #4) - 2 of 3 TS (on CMS 209, personnel #2 and #4) - 2 of 3 GS (on CMS 209, personnel #2 and #4) 2. The LD confirmed the findings above on 04/13/2023 around 03:00 pm. B. Based on lack of documentation and interview with the laboratory director (LD), the laboratory failed to establish a procedure for competency assessments for 5 of 6 testing personnel (TP) who performed testing in the areas of microbiology, immunology, chemistry and hematology from 01/01/2022 to the date of the survey. Findings include: 1. On the day of the survey, 04/13/2023 at 10:50 am. the laboratory could not provide competency assessment for 5 of 6 TP for each individual test performed in the chemistry and hematology departments from 01/01/2022 to 04/13 /2023. 2. The LD confirmed the findings above on 04/13/2023 around 03:00 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing personnel #5 (TP), the laboratory failed to perform calibration verification at least once every six months for 1 of 1 Advia 1800 and 1 of 1 Advia Centaur XP chemistry analyzer from 11/23/2020 to the date of survey. Findings include: 1. On the date of survey, 04/13/2023 at 12:54 pm, the laboratory could not provide calibration verification records for the required analytes tested on 1 of 1 Advia 1800 and 1 of 1 Advia Centaur XP chemistry analyzer from 11/23/2020 to 04/13/2023. 2. TP #5 confirmed the findings above on 04/13/2023 around 03:00 pm.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records, patient test reports, and interview with testing personnel #2 (TP), the laboratory failed to perform and document QC for 3 of 3 hematology white blood cell (WBC) differential analytes tested on the Cell Dyn 1600 performed from 11/23/2020 to the date of the survey. Findings include: 1. On the date of the survey, 04/13/2023 at 11:24 am, review of the laboratory's quality control records revealed that the laboratory failed to perform quality control for the following 3 of 3 hematology WBC differential analytes performed on the Cell Dyn 1600 from 11/23/2020 to 04/13/2023: - Monocytes - Eosinsophils - Basophils 2. Cell Dyn QC records showed the laboratory only performed the following QC for WBC differential results: - Neutrophils - Lymphocytes - Md/Mid/Mixed/Monocyte/Other %- Module A 3. Review of patient test reports revealed the laboratory reported the following WBC differential results: - Neutrophils - Lymphocytes - Monocytes - Eosinophils - Basophils 4. The laboratory performed 1,350 hematology examinations in 2022 (CMS 116 annual volume). 5. TP #2 confirmed the finding above on 04/13/2023 around 03:00 pm.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the Laboratory Director (LD), the laboratory failed to include the location of where erythrocyte sedimentation rate (ESR) examinations were performed on the patient test report from 11/23/2020 to the date of survey. Findings include: 1. On the date of survey, 04/13/2023 at 11:21 am, review of 1 of 1 hematology patient test reports revealed documentation of ESR results which are not part of the laboratory's approved test menu. 2. During the interview with the LD it was stated that, " the ESR results were performed at another facility, and the results were manually entered after the facility received a phone call from the testing facility." 3. Review of the 1 of 1 patient test report available revealed

	the final report did not include the address of where the ESR examinations were performed. 4. The LD confirmed the finding above on 4/13/2023 around 03:00 pm.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with the laboratory director (LD), the LD failed to ensure that quality control programs were established and maintained to identify failures in quality as they occur for 3 of 3 levels of QC performed on the Advia Centaur XP in chemistry on 09/12/2022. Findings: 1. On the day of survey, 04/13/2023 at 12:23 pm, review of the laboratory's quality control records revealed the laboratory failed to document the corrective action taken for 3 out of 3 levels of thyroid stimulating hormone QC failures on the Advia Centaur XP in chemistry on 09/12/2022. 2. The LD confirmed the findings above on 4/13 /2023 around 3:00 PM.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel qualification records and interview with the laboratory director (LD), the laboratory failed to ensure that 1 of 3 technical consultant met the qualification requirements (493.1411) for moderate complexity hematology and chemistry testing from 11/23/2020 to the date of survey. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or

	subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of personnel qualification records, hematology quality control (QC) records, and interview with the laboratory director(LD), the laboratory failed to ensure that 1 of 3 technical consultants (TC) met the required qualifications under C.F.R 493.1411 to perform the supervisory responsibilities of a TC for moderately complex testing in hematology and chemistry from 11/23/2020 to the date of survey. Findings include: 1. On the date of the survey, 04/13/2023 at 10:50 am, review of personnel qualification records revealed that 1 of 3 TC (CMS 209 TC # 2) did not meet the minimum required educational qualifications (493.1411) to perform the supervisory responsibilities of a TC for moderate complexity testing in hematology and chemistry from 11/23/2020 to 04/13/2023. 2. Review of personal credentials provided on the day of the survey revealed that TC#2 has and associates of science degree in medical laboratory technology. 3. Further review of hematology QC records revealed that TC#2 performed the duties of a TC from 11/23/2020 to 04/13/2023. 4. The LD confirmed the findings above on 04/13/2023 around 03:00 pm.