

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2023046	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Pathologist Bio-Medical Laboratories, Pllc	Street Address, City, State 3600 Gaston Ave, Wadley Tower, Suite 261, Dallas, 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	<p>Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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.</p>
D2138	<p>CYTOLOGY CFR(s): 493.855(b)</p> <p>Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-slide test.</p> <p>This STANDARD is not met as evidenced by: Based on review of Center for Medicare and Medicaid Services (CMS) 209 form, laboratory policy, College of American Pathologist (CAP) PAP proficiency testing (PT) records, and confirmed in staff interview, 1 of 10 testing personnel (TP-4) who perform gynecologic cytology failed to retest with a 20-slide test after failing the second testing event in 2020. Findings: 1. Review of the CMS 209 identified 10</p>

testing persons who perform gynecologic cytology. 2. Review of the laboratory's policy titled "Cytotechnologist / Pathologist Proficiency Testing Policy" revealed: "All testing personnel involved in the screening of Gyn Cytology samples are required, under 42 CFR 493.583 to participate successfully in an approved cytology proficiency testing program. Records of PT performance are maintained for at least 2 years. Records are kept for each individual participating in annual PT, including identification of those who are retested; records of remedial training; records of imposition of limitations on slide examination; and records of re-examination of slides, as required by CLIA. For any PT failures, please follow 42 CFR 493.855*. The Medical Director will verify receipt of Proficiency Test results and ensure that for any non-passing scores the appropriate remedial action is taken as specified under 42 CFR 493.855. Reference: * (1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails to an annual proficiency testing event, the laboratory must schedule a retesting event which must take place no more than 45 days after receipt of the notification failure. (2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again tested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented. (3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent. (c) If a laboratory fails to ensure that individuals are tested of those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part." 3. Review of CAP PAP PT records for 2020 and 2021 revealed TP-4 scored the following scores: Annual test session 9/21/2020: score 85%; unsatisfactory Retest 11/09/2020: score 85%; unsatisfactory Annual 10-slide test session 08/31/2021: score 100%; satisfactory TP-4 failed to retest with a 20-slide test after failing the second testing event in 2020 as required in CFR 493.855. 4. During an interview on 09/30 /2021 at 11:30 am, the Senior Manager Quality, Safety/Compliance stated that the laboratory was unaware that TP-4 had failed the annual PAP PT testing event and the retest in 2020. She stated that TP-4 never informed the laboratory of the failures. During a phone interview on 10/05/2021 at 3:20 pm, the Senior Manager Quality, Safety/Compliance stated that the annual event in 2021 was a 10-slide test because the laboratory was unaware of the failures in 2020. This confirmed the above findings. Word Key: PAP: Papanicolaou Gyn: gynecologic

D2142

CYTOLOGY
CFR(s): 483.855(b)(1)

An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set.

This STANDARD is not met as evidenced by:
 Based on review of Center for Medicare and Medicaid Services (CMS) 209 form, laboratory policy, College of American Pathologist (CAP) PAP proficiency testing (PT) records, and confirmed in staff interview, 1 of 10 testing personnel (TP-4) who perform gynecologic cytology failed to achieve greater than 90% on a 10-slide test for their annual testing event in 2020 (September). Findings: 1. Review of the CMS 209 identified 10 testing persons who perform gynecologic cytology. 2. Review of the laboratory's policy titled "Cytotechnologist / Pathologist Proficiency Testing Policy" revealed: "All testing personnel involved in the screening of Gyn Cytology samples are required, under 42 CFR 493.583 to participate successfully in an approved cytology proficiency testing program. Records of PT performance are maintained for at least 2 years. Records are kept for each individual participating in annual PT, including identification of those who are retested; records of remedial training; records of imposition of limitations on slide examination; and records of re-examination of slides, as required by CLIA. For any PT failures, please follow 42 CFR 493.855*. The Medical Director will verify receipt of Proficiency Test results and ensure that for any non-passing scores the appropriate remedial action is taken as specified under 42 CFR 493.855. Reference: * (1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails to an annual proficiency testing event, the laboratory must schedule a retesting event which must take place no more than 45 days after receipt of the notification failure. (2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again tested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented. (3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent. (c) If a laboratory fails to ensure that individuals are tested of those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part." 3. Review of CAP PAP PT records revealed TP-4 scored an unsatisfactory score of 85% for their annual test session on 09/21 /2020. TP-4 failed to achieve greater than 90% on a 10-slide test for their 2020 annual testing event. 4. During an interview on 09/30/2021 at 11:30 am, the Senior Manager Quality, Safety/Compliance confirmed the above findings. Word Key: PAP: Papanicolaou Gyn: gynecologic

D2144

CYTOLOGY
 CFR(s): 493.855(b)(2)

An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set.

This STANDARD is not met as evidenced by:

Based on review of Center for Medicare and Medicaid Services (CMS) 209 form, laboratory policy, College of American Pathologist (CAP) PAP proficiency testing (PT) records, and confirmed in staff interview, 1 of 10 testing personnel (TP-4) who perform gynecologic cytology failed to achieve greater than 90% on a 10-slide test for their second testing event in 2020 (September). Findings: 1. Review of the CMS 209 identified 10 testing persons who perform gynecologic cytology. 2. Review of the laboratory's policy titled "Cytotechnologist / Pathologist Proficiency Testing Policy" revealed: "All testing personnel involved in the screening of Gyn Cytology samples are required, under 42 CFR 493.583 to participate successfully in an approved cytology proficiency testing program. Records of PT performance are maintained for at least 2 years. Records are kept for each individual participating in annual PT, including identification of those who are retested; records of remedial training; records of imposition of limitations on slide examination; and records of re-examination of slides, as required by CLIA. For any PT failures, please follow 42 CFR 493.855*. The Medical Director will verify receipt of Proficiency Test results and ensure that for any non-passing scores the appropriate remedial action is taken as specified under 42 CFR 493.855. Reference: * (1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails to an annual proficiency testing event, the laboratory must schedule a retesting event which must take place no more than 45 days after receipt of the notification failure. (2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again tested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented. (3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent. (c) If a laboratory fails to ensure that individuals are tested of those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part." 3. Review of CAP PAP PT records revealed TP-4 scored an unsatisfactory score of 85% for their second testing event on 11/09/2020. TP-4 failed to achieve greater than 90% on a 10-slide test for their second testing event in 2020. 4. During an interview on 09/30/2021 at 11:30 am, the Senior Manager Quality, Safety/Compliance confirmed the above findings. Word Key: PAP: Papanicolaou Gyn: gynecologic

D2145

CYTOLOGY

CFR(s): 493.855(b)(2)

For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and

This STANDARD is not met as evidenced by:

Based on review of Center for Medicare and Medicaid Services (CMS) 209 form, laboratory policy, College of American Pathologist (CAP) PAP proficiency testing (PT) records, laboratory personnel records, and confirmed in staff interview, the laboratory failed to provide and document remedial training and education in the area of failure for 1 of 10 testing personnel (TP-4) who perform gynecologic cytology in 2020. Findings: 1. Review of the CMS 209 identified 10 testing persons who perform gynecologic cytology. 2. Review of the laboratory's policy titled "Cytotechnologist / Pathologist Proficiency Testing Policy" revealed: "All testing personnel involved in the screening of Gyn Cytology samples are required, under 42 CFR 493.583 to participate successfully in an approved cytology proficiency testing program. Records of PT performance are maintained for at least 2 years. Records are kept for each individual participating in annual PT, including identification of those who are retested; records of remedial training; records of imposition of limitations on slide examination; and records of re-examination of slides, as required by CLIA. For any PT failures, please follow 42 CFR 493.855*. The Medical Director will verify receipt of Proficiency Test results and ensure that for any non-passing scores the appropriate remedial action is taken as specified under 42 CFR 493.855. Reference: * (1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails to an annual proficiency testing event, the laboratory must schedule a retesting event which must take place no more than 45 days after receipt of the notification failure. (2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again tested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented. (3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent. (c) If a laboratory fails to ensure that individuals are tested of those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b) (3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part." 3. Review of CAP PAP PT records for 2020 revealed TP-4 scored the following scores: Annual test session 9/21/2020: score 85%; unsatisfactory Retest 11/09/2020: score 85%; unsatisfactory Review of personnel records for TP-4 revealed no documentation of remediation and education in the area of failure. 4. During an interview on 09/30/2021 at 11:30 am, the Senior Manager Quality, Safety/Compliance stated that the laboratory was unaware that TP-4

had failed the annual PAP PT testing event and the retest in 2020. She stated that TP-4 never informed the laboratory of the failures, therefore no remediation and education was given to TP-4. This confirmed the above findings. Word Key: PAP: Papanicolaou
Gyn: gynecologic