

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION**

In The Matter Of:

Microbac Laboratories, Inc.	:	
Baltimore Division	:	Environmental Laboratory Accreditation
2101 Van Deman Street	:	
Baltimore, MD 21224-6697	:	

CONSENT ORDER AND AGREEMENT

This Consent Order and Agreement is entered into this 16th day of September 2013, by and between the Commonwealth of Pennsylvania, Department of Environmental Protection ("Department") and Microbac Laboratories, Inc. ("Microbac") regarding Microbac's Baltimore Division ("Microbac Baltimore"). For the purposes of this Consent Order and Agreement ("COA"), the Department and Microbac are sometimes referred to collectively as the "Parties".

The Department has found and determined the following:

A. The Department is the agency with the duty and authority to administer and enforce the Act of June 29, 2002, P.L. 596, 27 Pa.C.S. §§ 4101 – 4113 ("Environmental Laboratory Accreditation Act"), the Pennsylvania Safe Drinking Water Act, the Act of May 1, 1984, P.L. 206 as amended, 35 P.S. § 721.1 *et seq.* ("Safe Drinking Water Act" or "SDWA"); Section 1917-A of the Administrative Code of 1929, Act of April 9, 1929, P.L. 177, as amended, 71 P.S. § 510-17, and the rules and regulations promulgated pursuant to each of these Acts.

B. Microbac owns and operates a network of environmental laboratories, as the term "environmental laboratory" is defined by Section 4102 of the Environmental Laboratory Accreditation Act (27 Pa.C.S. § 4102). One of Microbac's laboratories, Microbac Baltimore, has a business address of 2101 Van Deman Street, Baltimore, MD 21224-6697.

C. On July 28, 2006, Microbac applied for National Environmental Laboratory Accreditation Program ("NELAP") accreditation for its Microbac Baltimore laboratory with the Department in accordance with the Environmental Laboratory Accreditation Regulations, 25 Pa. Code Chapter 252, § 252.5 and the Act, 27 Pa. C.S. § 4104, and Microbac Baltimore is assigned Laboratory Accreditation Number 68-00339 (PADWIS ID # 68339).

D. On August 8, 2006, the Department granted accreditation in accordance with 25 Pa. Code § 252.5, the 2003 National Environmental Laboratory Accreditation Conference ("NELAC") Standard, and the Act of June 29, 2002 (P.L. 596, No. 90).

E. 25 Pa. Code § 252.5 in relevant part provides:

(a) An environmental laboratory may apply to the Department for NELAP accreditation for the fields of accreditation for which the Department offers accreditation.

(b) An environmental laboratory seeking NELAP accreditation shall:

(2) Comply with subchapter E (relating to proficiency test study requirements).

(3) Comply with Subchapter F (relating to onsite assessment requirements).

(4) Comply with Subchapter G (relating to miscellaneous provisions).

(5) Comply with the current edition of the NELAC Standard or TNI Standard.

(d) An environmental laboratory receiving NELAP accreditation from the Department may only test or analyze environmental samples within the fields of accreditation authorized by the accreditation received from the Department.

F. Effective July 1, 2011, the 2009 TNI Standard ("TNI" refers to The NELAC Institute) became the current edition of the NELAC/TNI standard. Prior to July 1, 2011, the effective edition of the NELAC Standard was the 2003 NELAC Standard, effective July 1, 2005. The Department delayed the implementation date of the 2009 TNI Standard until at least September 1, 2011.

G. The Department conducted three on-site assessments of Microbac Baltimore on March 23 – 26, 2009, February 18 – 19, 2010, and August 8 – 10, 2011 and notified Microbac Baltimore of the alleged violations found during these on-site assessments in Reports of an On-Site Assessment (“OSRs”) issued April 24, 2009, March 31, 2010, and September 13, 2011. Microbac Baltimore provided satisfactory corrective actions to the alleged violations and provided evidence that demonstrated correction of the alleged violations outlined in the Department’s OSRs.

H. On April 8-11, 2013, Department employees conducted an unannounced on-site assessment (“April 2013 Assessment”) of Microbac Baltimore to determine compliance with 25 Pa. Code Chapter 252 and the 2009 TNI Standard.

I. During the Department’s April 2013 Assessment, the Department alleged that Microbac Baltimore failed to meet conditions of its accreditation by failing to comply with both the 25 Pa. Code Chapter 252 (“Chapter 252”) and the 2009 TNI Standard, requirements for accreditation.

J. On April 11, 2013, during the last day of its on-site assessment, the Department reviewed its findings from the on-site assessment with Microbac Baltimore.

K. On June 13, 2013, the Department notified Microbac in writing of the findings of the on-site assessment in a Notice of Violation (“June 2013 NOV”) and in a Report of an On-Site Assessment (“April 2013 OSR”).

L. On July 19, 2013, the Department issued amendments to the June 2013 NOV (“July 2013 Amended NOV”) and the April 2013 OSR (“April 2013 AOSR”). A true and

correct copy of the July 2013 Amended NOV and April 2013 AOSR are attached hereto, made a part hereof and marked Exhibits A and B.

M. Pursuant to the Environmental Laboratory Accreditation Act, 27 Pa. C.S. § 4103(b), an environmental laboratory must be accredited and be in compliance with the provisions of Chapter 252 and the 2009 TNI Standard in order to generate data or perform analyses.

N. During the April 2013 Assessment, the Department allegedly found numerous deviations, of which some were repeat deviations previously cited by the Department during the on-site assessments conducted in March 2009, February 2010 and August 2011 of Microbac Baltimore.

O. During the April 2013 Assessment, the Department alleged that Microbac Baltimore violated the general, the method-specific, the quality control and the technical, requirements of the applicable standards by failing to ensure compliance with the essential standards outlined in the applicable technical modules, mandated methods, and/or regulations, whichever are more stringent, as required by 2009 TNI Standard, Volume 1, Module 2 ("TNI V1M2") § 5.9.3.c.

P. Specifically, the Department alleged that Microbac Baltimore: (1) failed to meet the method-specific requirements as described in Deviations RM1, RM2 (for Methods 8081/8082), RM6, RM7, and RM8 of the April 2013 AOSR; (2) failed to meet the regulatory requirements of 40 CFR Parts 141 and 136 and 25 Pa. Code Chapters 109 and 252 as described in Deviations RM10 – RM13, G21, and QS43 of the April 2013 AOSR; and (3) failed to meet the requirements outlined in the technical modules of the 2009 TNI Standard as described in

Deviations C30, C41, C45, C47, C51, C57, C62, C70, C100, C101, C143, M15, and M20 – M22 of the April 2013 AOSR.

Q. In addition, during the April 2013 Assessment, the Department alleged that Microbac Baltimore: (1) failed to inform its secondary accreditation bodies (“ABs”) within 30 days of any changes to the laboratory’s accreditation as described in Deviation RM9 of the April 2013 AOSR; (2) failed to implement its quality system and all quality control procedures as required by the 2009 TNI Standard as described in Deviation G4 of the April 2013 AOSR; (3) failed to ensure that the designated technical manager and quality assurance officer fulfill the requirements of TNI V1M2 as described in Deviations QS5 –QS9, QS11, QS20, QS33, QS43, QS122 – QS124, and QS132 of the April 2013 AOSR; (4) failed to ensure that analytical results reported on test reports meet the requirements of TNI V1M2 and 25 Pa. Code Chapter 252 as described in Deviations QS182, and QS186 – QS189 of the April 2013AOSR; and (4) failed to ensure a document control and recordkeeping system that meet the requirements of TNI V1M2 as described in Deviations T3,T4,T11,T16, T17, T22, T23, T133 and T65 of the April 2013 AOSR.

R. On June 27, 2013, representatives from Microbac and the Department met to discuss the alleged violations outlined in the April 2013 OSR. At the conclusion of the June 27 meeting, Microbac agreed: (1) to voluntarily withdraw all of Microbac Baltimore’s fields of accreditation under the scope of 25 Pa. Code Chapter 252, § 252.3(a) on a temporary basis effective July 2, 2013 at 5:00 p.m.; and (2) to hire an independent third party auditor to conduct a thorough assessment of the inorganic non-metals, microbiology, and trace metals fields of accreditation.

S. Pursuant to the Environmental Laboratory Accreditation Act, 27 Pa. C.S. § 4104, the Department has the power and duty to enforce the TNI Standards and the Chapter 252 environmental laboratory accreditation program requirements.

T. The alleged violations described in Paragraphs K through Q subject Microbac to enforcement actions under Section 4110(b) of the Environmental Laboratory Accreditation Act and §§ 252.702(b)(2), (3), and (12) of Chapter 252.

After full and complete negotiation of all matters set forth in this COA and upon mutual exchange of covenants contained herein, the Parties desiring to avoid litigation and intending to be legally bound, it is hereby ORDERED by the Department and AGREED to by Microbac as follows:

1. Authority. This COA is an Order of the Department, authorized and issued pursuant to Section 4104 of the Environmental Laboratory Accreditation Act, 27 Pa. C.S. § 4104.

2. Findings.

a. Microbac agrees that the findings in Paragraphs A through Q are true and correct. In any matter or proceeding involving Microbac and the Department, Microbac shall not challenge the accuracy or validity of these findings.

b. The Parties do not authorize any other persons to use the findings in this COA in any matter or proceeding.

3. Corrective Action.

a. Microbac shall hire an independent third party NELAP-qualified auditor ("Third Party Auditor") to conduct a full and complete audit and assessment ("Comprehensive Audit") of

Microbac Baltimore's conditions of accreditation including analytical testing reports issued by Microbac since January 2012, sample receiving, and reporting procedures, at the Microbac Baltimore laboratory as such conditions are set forth in its accreditation and by the Environmental Laboratory Accreditation Act, 27 Pa. C.S. § 4106.

(i.) The Comprehensive Audit undertaken by Microbac Baltimore must include all fields of accreditation for which Microbac Baltimore desires to have reinstated. Each Comprehensive Audit shall include an evaluation of the effectiveness and maintenance of the corrective actions implemented after the Department's March 2009, February 2010, August 2011, and April 2013 on-site assessments as applicable to the fields of accreditation covered by the specific Comprehensive Assessment.

(iii.) Microbac shall provide a copy of each and every Third Party Auditor's final Audit report within five (5) business days of its receipt of each such final report(s) to the Department for the Department's review, modification, and/or approval.

(iv.) Once the Department reviews and approves or modifies the Third Party Auditor's final Comprehensive Audit report as would be completed for a new applicant, Microbac shall develop and implement corrective actions to correct all deviations identified in the Third Party Auditor's final Comprehensive Audit Report and the Department's April 2013 AOSR to ensure current and future compliance with Microbac Baltimore's conditions of accreditation.

(v.) Microbac shall provide a corrective action plan and implementation schedule for the above-referenced corrective actions to the Department for review, modification, and/or approval.

b. The Third Party Audit required by paragraph 3.(a) above shall include a comprehensive investigation of all analytical results analyzed in accordance with the TNI and pursuant to the accreditation requirements of the Department by Microbac Baltimore since January 1, 2012 in order to determine compliance with the requirements of the 2009 TNI Standard and 25 Pa Code §§ 252.705(b), 707, and 708(a) for all work associated with the alleged deficiencies outlined in the April 2013 AOSR.

(i.) In the organics section of the laboratory, the Third Party Auditor's review of analytic results shall include all field of the Department's accreditation.

(ii.) In the metals, wet chemistry and microbiology sections of the laboratory, the Third Party Auditor's review of analytic results shall focus on those areas identified by the Third Party Auditor as having significant deficiencies, non-compliance with the applicable standards and those areas where the Auditor recommends corrective actions.

(iii.) In all sections of the laboratory, the Third Party Auditor's review of analytic reports shall determine compliance with the requirements of the 2009 TNI Standard and 25 Pa. Code Chapter 252 by at least an evaluation of the following:

- Test report components including, but not limited to, the requirements of TNI V1M2: 5.10
- Identification of test results obtained from a subcontract laboratory, including the laboratory's PA-DEP Laboratory ID#
- Identification of the laboratory's accreditation status (both Microbac and any subcontract laboratory) at the time of analysis
- Manual integrations of organic chromatography

- Compliance with regulatory, standard, and method requirements of sample collection, receipt, and storage, such as holding time, sample container, chemical and thermal preservation requirements, etc.
- Quality control (such as method blanks, laboratory control samples, calibration verifications, matrix spikes, and sample duplicates)
- Instrument and equipment specifications including initial calibration, verification, and calculation of final sample results
- Reporting and notification of all SDWA compliance results as required by 25 Pa. Code § 252.708(a) and 25 Pa. Code Chapter 109.

(iv.) The Third Party Auditor's Audit Report(s) shall include a section summarizing the outcome of the investigation of the historic analytical reports including, but not limited to, the following items:

- Summary of procedures used to evaluate the sample results and analytical reports
- Identification of all samples reviewed during the evaluation
- Identification of all client names and addresses for each sample included in the evaluation
- Summary of the findings from the investigation, including compliance or non-compliance for a particular sample

(v.) Microbac Baltimore shall reissue all analytical test reports found to be deficient by the Third Party Auditor's final Audit Report required in this COA to both the client and the Department within thirty (30) days of completion of the Audit.

c. Before requesting the Department to reinstate accreditation for its organics fields of accreditation, Microbac Baltimore shall submit for Department approval on a Part 4 –

Add/Change Laboratory Supervisor application a qualified laboratory supervisor(s) not employed by Microbac Baltimore as of April 11, 2013 to serve as the laboratory supervisor(s) for the organic chemistry fields of accreditation.

d. With regard to any document that Microbac is required to submit to the Department, the Department will review, approve or modify the document in writing. If any document is found by the Department to be deficient, Microbac shall, within 14 days of receipt of the Department's written response, revise and resubmit to the Department a revised document addressing the Department's concerns. The Department will approve, disapprove, or modify the revised document in writing. Once approved, the resulting documents will become part of this COA and will be enforceable as such.

4. Civil Penalty Assessment. Within 30 days of the date of this COA, Microbac shall pay a civil penalty of \$ 60,000.00. This payment is in settlement of the Department's claim for civil penalties for the alleged violations described in Paragraphs N through Q.

a. The payment shall be made by corporate check or the like made payable to the Commonwealth of Pennsylvania and sent to: Aaren Alger, Chief, Laboratory Accreditation Program, Bureau of Laboratories, Department of Environmental Protection, 2575 Interstate Drive, P.O. Box 1467 Harrisburg, PA 17105.

5. Stipulated Civil Penalties.

a. In the event that Microbac fails to comply with any term or provision of this COA, Microbac shall be in violation of this COA and, in addition to other applicable remedies, shall pay a civil penalty in the amount of \$ 250 per each violation.

b. Stipulated civil penalty payments shall be payable monthly on or before the fifteenth day of each succeeding month. All payments shall be made by corporate check or the like made payable to the Commonwealth of Pennsylvania and sent to: Aaren Alger, Chief, Laboratory Accreditation Program, Bureau of Laboratories, Department of Environmental Protection, 2575 Interstate Drive, P.O. Box 1467 Harrisburg, PA 17105.

c. Any payment under this paragraph shall neither waive Microbac's duty to meet its obligations under this COA nor preclude the Department from commencing an action to compel Microbac's compliance with the terms and conditions of this COA. The payment resolves only Microbac's liability for civil penalties arising from the violation of this COA for which the payment is made.

d. Stipulated civil penalties shall be due automatically and without notice.

6. Remedies.

a. In the event that Microbac fails to comply with any term or provision of this COA by failing to ensure that all alleged violations are corrected, or fails to comply with the terms or provisions of paragraphs 3 or 4, Microbac shall withdraw its application for accreditation in the Department's Laboratory Accreditation Program. Microbac may choose to re-apply for accreditation and shall be subject to the fees associated with an initial application for accreditation and an on-site evaluation.

b. In the event Microbac fails to comply with any provision of this COA, the Department may, in addition to the remedies prescribed herein, pursue any remedy available for a violation of an order of the Department, including an action to enforce this COA. The failure of the Department to pursue any remedy shall not be deemed to be a waiver of that remedy.

7. Reservation of Rights. The Department reserves the right to require additional measures to achieve compliance with applicable law. Microbac reserves the right to challenge any action which the Department may take to require those measures.

8. Liability of Operator. Microbac shall be liable for any violations of the COA, including those caused by, contributed to, or allowed by its officers, agents, employees, or contractors. Except as provided in paragraph 9(c), Microbac also shall be liable for any violation of this COA caused by, contributed to, or allowed by its successors and assigns.

9. Transfer of Site.

a. The duties and obligations under this COA shall not be modified, diminished, or terminated or otherwise altered by the transfer of any legal or equitable interest in Microbac or any part thereof.

b. If Microbac intends to transfer any legal or equitable interest in Microbac which is affected by this COA, Microbac shall serve a copy of this COA upon the prospective transferee of the legal and equitable interest at least thirty (30) days prior to the contemplated transfer and shall simultaneously inform the Department of such intent.

c. The Department may agree to modify or terminate Microbac's duties and obligations under this COA upon transfer of Microbac. Microbac waives any right that it may have to challenge the Department's decision in this regard.

10. Correspondence with Department. All correspondence with the Department concerning this COA shall be addressed to:

US Postal Service:

Aaren S. Alger
Laboratory Accreditation Program
Department of Environmental Protection

All other modes of delivery:

Aaren S. Alger
Laboratory Accreditation Program
Department of Environmental Protection

Bureau of Laboratories
PO Box 1467
Harrisburg, PA 17105-1467

Bureau of Laboratories
2575 Interstate Drive
Harrisburg, PA 17110-9332

11. Correspondence with Microbac. All correspondence with Microbac concerning this COA shall be:

Addressed to:
Robert Colvin, Managing Director
Microbac Laboratories, Inc.
Baltimore Division
2101 Van Deman Street
Baltimore, MD 21224-6697

With a copy addressed to:
Colleen Grace Donofrio
Babst Calland Clements and Zomnir, PC
380A Tylers Mill Road
Sewell, NJ 08080

Microbac shall notify the Department whenever there is a change in the contact person's name, title, or address. Service of any notice or any legal process for any purpose under this COA, including its enforcement, may be made by mailing a copy by certified mail to the above address.

12. Severability. The paragraphs of this COA shall be severable and should any part hereof be declared invalid or unenforceable, the remainder shall continue in full force and effect between the Parties.

13. Entire Agreement. This COA shall constitute the entire integrated agreement of the Parties. No prior or contemporaneous communications or prior drafts shall be relevant or admissible for purposes of determining the meaning or extent of any provisions herein in any litigation or any other proceeding.

14. Attorney Fees. The Parties shall bear their respective attorney fees, expenses and other costs in the prosecution or defense of this matter or any related matters, arising prior to execution of this COA.

15. Modifications. No changes, additions, modifications, or amendments of this COA shall be effective unless they are set out in writing and signed by the Parties hereto.

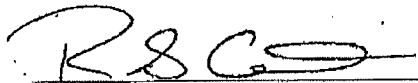
16. Titles. A title used at the beginning of any paragraph of this COA may be used to aid in the construction of that paragraph, but shall not be treated as controlling.

17. Decisions Under Consent Order. Any decision which the Department makes under the provisions of this COA is intended to be neither a final action under 25 Pa. Code § 1021.2, nor an adjudication under 2 Pa. C.S. § 101. Any objection which Microbac may have to the decision will be preserved until the Department enforces this COA.

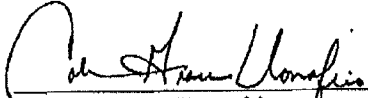
IN WITNESS WHEREOF, the Parties hereto have caused this COA to be executed by their duly authorized representatives. The undersigned representatives of Microbac certify under penalty of law, as provided by 18 Pa. C.S. § 4904, that they are authorized to execute this COA on behalf of Microbac; that Microbac consents to the entry of this COA as a final ORDER of the Department; and that Microbac hereby knowingly waives its right to appeal this COA and to challenge its content or validity, which rights may be available under Section 4 of the Environmental Hearing Board Act, Act of July 13, 1988, P.L. 530, 35 P.S. § 7514; the Administrative Agency Law, 2 Pa. C.S. § 103(a) and Chapter 5, Subchapter A and Chapter 7, Subchapter A; or any other provisions of law. Signature by Microbac's attorney certifies only that this COA has been signed after consulting with counsel.

FOR MICROBAC:

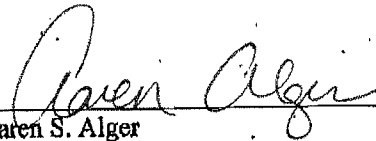
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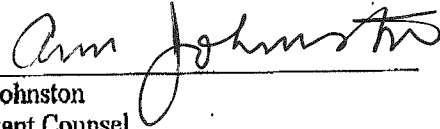
Robert S. Crookston
Senior VP, Microbac Laboratories, Inc.



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Chief, Laboratory Accreditation Program



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