

**ATTORNEY GENERAL OF THE STATE OF NEW YORK**

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In the Matter of  
Laboratory Corporation of America  
Assurance No.: 15-169

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**ASSURANCE OF DISCONTINUANCE  
UNDER EXECUTIVE LAW  
SECTION 63, SUBDIVISION 15**

Pursuant to the provisions of Section 63(12) of the Executive Law and 10 N.Y.C.R.R. § 58-1.7(b), Eric T. Schneiderman, Attorney General of the State of New York, caused an inquiry to be made into certain business practices of Laboratory Corporation of America (“LabCorp”). Based upon that inquiry, the Office of the Attorney General (“the OAG”) has made the following findings, and LabCorp has agreed to modify its business practices and comply with the following provisions of this Assurance of Discontinuance (“Assurance”).

**I. THE ATTORNEY GENERAL’S FINDINGS**

**A. Background**

1. In March 2015, The OAG commenced its investigation into LabCorp’s business practices, obtaining documents and testimony via subpoena, after receiving a complaint that a separate company, Direct Laboratory Services, LLC (“DirectLabs”), was offering a wide range of clinical laboratory testing directly to New York consumers, without any examination by a licensed health care provider (“HCP”) acting within the scope of their license (such practice shall be referred to herein as “direct access testing”). The OAG’s investigation revealed that DirectLabs’ customers received requisitions for testing that they brought to LabCorp patient

service centers (“PSCs”) for fulfillment. This conduct, along with the conduct described in Paragraphs 1 through 21 below is defined as the “Covered Conduct.”

2. LabCorp is a Delaware corporation with its principal place of business at 531 South Spring Street, Burlington, North Carolina 27215. LabCorp is, in its own words, “the world’s leading healthcare diagnostics company, providing comprehensive clinical laboratory services through LabCorp Diagnostics and end-to-end drug development support through Covance Drug Development.”

3. New York State law generally allows clinical laboratories to perform tests, such as blood or urine analysis, only upon the request of an authorized HCP acting within the scope of their license.<sup>1</sup> The public policy rationale for limiting who can order tests is compelling. Licensed HCPs, ordering tests within the scope of a physician-patient relationship, are able to identify: (a) which tests will be clinically useful based on the entirety of a patient’s medical condition and symptoms; (b) how and when such tests can lead to clinically meaningful results (*e.g.*, when testing should be performed to get a valid result and whether other tests should be ordered to put the results in further context); and (c) whether the results of the testing are likely to reflect a false-positive or false-negative (*i.e.*, the patient is likely to have the condition despite testing negative, or the patient is unlikely to have the condition despite testing positive). In other words, HCP oversight and involvement protects patients against unnecessary testing and ensures that the test results are properly understood and utilized.

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<sup>1</sup> A very narrow exception to this requirement allows New York consumers to purchase laboratory testing on their own (“direct access testing”), but only if the test is for the same purpose as a test or collection device that has been approved by the U.S. Food and Drug Administration (“FDA”) for over-the-counter sales without a prescription from a qualified health care practitioner, such as a home pregnancy test. The overwhelming majority of the tests that DirectLabs offered in New York, however, did not fall within this limited exception.

4. The misunderstandings that may ensue from a consumer's inability to recognize the clinical implications of a test result – for example, incorrectly believing one is free from an infectious disease after receiving a false negative result – can endanger not only the health of the individual tested, but also the health of those around them.

#### **B. DirectLabs' New York Business Model**

5. Until March 2015, DirectLabs operated an online and telephone service that enabled New York consumers to circumvent New York State law and order diagnostic clinical laboratory testing themselves without visiting a licensed HCP. DirectLabs, which is neither a medical provider nor a laboratory, offered over 250 clinical laboratory tests and testing packages in New York, including tests for parasites, heavy metals, thyroid levels, vitamin levels, various cancer markers, other specific diseases (such as celiac disease and rheumatoid arthritis) and various "comprehensive" profiles or panels (for general wellness, "metabolic" panels, and gastrointestinal function). Most of these tests are not approved by the FDA for over-the-counter sale, including tests for cancer screening, thyroid disease, and serious cardiac events.

6. DirectLabs' Internet home page has stated since at least 2012: "Your Doctor's Orders Not Necessary." Its web page for New York customers stated from approximately July 2013 through March 2015: "**DirectLabs***Access* provides the necessary doctor's orders for your online lab tests and makes the results available directly to you."

7. After selecting all tests they wished to have performed through the DirectLabs website (or over the phone), customers proceeded to check out. Upon checking out, DirectLabs charged them a \$24 "Access Portal Charge." Customers then received a requisition form for the tests they selected, which they brought to a LabCorp PSC to have the testing performed. Customers paid LabCorp the price of the tests, as listed on the DirectLabs website.

8. DirectLabs' exclusive laboratory partner in New York was LabCorp. DirectLabs instructed its customers to verify that there was a LabCorp location near them before placing their order, and to bring DirectLabs-issued requisitions to a LabCorp PSC, where they would be billed for the cost of the testing at special rates for DirectLabs customers.

9. Once DirectLabs' customers purchased the tests and paid the Access Portal Charge, they received an email confirming their order. This email stated: "You MUST print your requisition from your **MyDLS®** Account and bring it and payment to a **LABCORP** PSC. If you bring your requisition to a lab other than LabCorp, you will be responsible for the bill from that lab" (emphasis in original). The email provided a link to find the nearest LabCorp PSC.

10. After DirectLabs' customers brought their requisitions to LabCorp PSCs and had specimens drawn, LabCorp made the results available to DirectLabs through an online portal.

11. DirectLabs provided each of its more than 1,100 New York customers with a laboratory testing requisition form that could be presented at any LabCorp PSC. LabCorp then processed these customers' blood or urine specimens.

### **C. The Arrangement Between LabCorp and DirectLabs**

12. In 2012, LabCorp contracted with DirectLabs to process requisitions for laboratory testing submitted by DirectLabs in New York, at a fee schedule negotiated by the parties. Pursuant to a separate data management agreement, LabCorp provided DirectLabs access to an electronic interface that enabled DirectLabs to generate requisitions for laboratory testing, transmit customer information to LabCorp, and receive its customers' test results. LabCorp also provided DirectLabs with requisition forms, report papers, and printing accessories.

13. LabCorp's contract with DirectLabs that was effective in New York required that "[b]efore submitting a requisition for laboratory testing ... [Direct Labs] shall ensure that all requests for tests have been reviewed and approved by a physician licensed in the applicable patient's state of residence."

14. LabCorp considered DirectLabs to be a "virtual account": a company not located in a typical medical practice that owns a web site that offers consumers direct access testing.

15. The name of a single individual, a New York chiropractor, appeared on all of the approximately 1,400 requisitions presented by DirectLabs customers at LabCorp PSCs in New York.

16. When DirectLabs customers appeared at New York LabCorp PSCs with DirectLabs-issued requisitions, LabCorp staff did not check whether a New York-licensed health care provider ("HCP") acting within the scope of their license requested the testing, or whether New York-licensed HCPs examined those patients,<sup>2</sup> before taking and examining specimens from these consumers.

17. Although the chiropractor's name appeared on the New York requisitions issued by DirectLabs and presented by consumers at LabCorp PSCs, in some instances for unknown reasons, the names of other non-New York HCPs appeared on requisitions generated internally by LabCorp.

18. Since 2009, LabCorp has maintained a diligence checklist for its "virtual accounts" in which LabCorp assesses, among other things, whether the account has a licensed health care provider on staff and contracted to order testing in each state, and how the account

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<sup>2</sup> Prior to setting up the account with DirectLabs, LabCorp checked to see whether the physicians designated as DirectLabs' state "medical directors," such as the New York chiropractor, were licensed. In addition, approximately once per year, LabCorp checked to see whether the physicians designated as DirectLabs' state medical directors were still licensed.

will document that the licensed ordering provider approved the request that a test be performed. LabCorp did not complete the diligence checklist for DirectLabs because it already had a contract with that entity that addressed these items.

19. Under New York State Department of Education regulations, chiropractors are legally authorized to order only certain laboratory tests. LabCorp processed approximately 130 tests listed on DirectLabs-issued requisitions that are outside a chiropractor's scope of practice, including tests for cancer antigen, rheumatoid arthritis factor, prostate specific antigen, and tacrolimus.

20. On March 25, 2015, shortly after receiving a subpoena from the OAG, DirectLabs informed LabCorp that it was discontinuing its operations in New York.

21. In October 2015, LabCorp terminated its contract with DirectLabs. At the time that it terminated its contract with DirectLabs, LabCorp had no other contracts with virtual accounts offering direct access testing to New York consumers through the Internet.

## **II. RELEVANT NEW YORK STATE LAW**

22. The New York State Executive Law prohibits "illegal or fraudulent acts" in the conduct of any business, trade or commerce, and allows the OAG to institute a special proceeding for restitution, damages, and/or injunctive relief against any party which has committed such acts. N.Y. Exec. Law § 63(12).

23. As a general matter,<sup>3</sup> a clinical laboratory in New York may examine specimens "only at the request" of a licensed physician or other specifically authorized individuals, such as dentists, podiatrists, and chiropractors, if it falls within their scope of practice. 10 N.Y.C.R.R. §

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<sup>3</sup> A limited exception, which is not relevant here, is set forth in Public Health Law § 576-B, "where the service is for the same purpose as a test or collection device that has been approved or cleared by the [FDA] for sale or distribution to the public on a direct or over-the-counter basis."

58-1.7(b) (regulations promulgated by the New York State Department of Health pursuant to Title 5 of the New York Public Health Law (“Clinical Laboratory and Blood Banking Services”)).

24. Pursuant to the “Guidelines for Clinical Laboratory Business Model Compliance” of the Wadsworth Center of the New York State Department of Health, which regulates and oversees clinical diagnostic laboratories that test specimens from New York State patients, a provider authorizing laboratory testing must use the result of the testing in his/her professional practice, be “substantially and meaningfully involved . . . in ordering and interpretation of laboratory tests,” and not have a “compensation arrangement with the analytical laboratory.”<sup>4</sup> The Wadsworth Center’s Guidelines define “substantially and meaningfully involved” as the Department of Health’s “expectation for practitioner involvement with the patient within a patient-physician relationship, minimally including the practitioner taking a medical history and maintaining patient-specific medical records.”

25. Pursuant to Section 577(1)(b) of the Public Health Law, a clinical laboratory’s permit or certificate of qualification may be revoked, suspended, limited or annulled if it has: “accepted or permitted to be accepted a specimen or assignment for clinical laboratory examination from or rendered a report thereon to a person or persons not authorized by law to submit such assignment or specimen or receive such report.”

26. The OAG contends that by examining specimens when it knew or should have known that an authorized provider had not requested the testing, as set forth in the OAG’s findings in Paragraphs 1 through 21, LabCorp violated Executive Law Section 63(12) and 10 N.Y.C.R.R. § 58-1.7(b).

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<sup>4</sup> Available at <http://www.wadsworth.org/labcert/elep/Administrative/NYSBusinessPracticeGuidelines.pdf>.

**NOW, WHEREAS,** LabCorp neither admits nor denies the Attorney General's findings in Paragraphs 1 through 21 above; and

**WHEREAS,** New York laws restricting direct access testing confer important consumer and public health protections; and

**WHEREAS,** LabCorp has cooperated with the OAG's investigation; and

**WHEREAS,** in consideration of the obligations incurred by LabCorp herein, the Attorney General is willing to accept the terms of this Assurance under Executive Law Section 63(15) and, subject to the monitoring provision of Paragraph 40 below, agrees to discontinue his investigation relating to the Covered Conduct and not re-recommence any investigation against LabCorp related to the Covered Conduct, so long as LabCorp complies with the terms of this Assurance; and

**WHEREAS,** the parties each believe that the obligations imposed by this Assurance are prudent and appropriate; and

**WHEREAS,** the Attorney General has determined that this Assurance is in the public interest.

**IT IS HEREBY UNDERSTOOD AND AGREED,** by and between the parties that:

**III. PROSPECTIVE RELIEF**

27. Effective immediately, LabCorp's New York PSCs shall not accept specimens for examination pursuant to requisitions or other orders that it knows to be issued by: (a) DirectLabs; or (b) any other individual or entity that it knows is engaged in the business of providing direct access testing services primarily through the Internet.

28. Within 60 (sixty) days of the Effective Date, LabCorp shall implement an internal process in New York to verify that requests for testing that LabCorp processes have been made

by licensed HCPs acting within their scope of practice. Such internal process shall verify, on an annual basis, that: (i) Health Care Providers (“HCPs”) who hold accounts with LabCorp in New York are licensed in their profession in New York; and (ii) tests that New York LabCorp account holders are allowed to order are within the scope of practice of their profession, as defined by the New York State Education Department (“NYSED”), to the extent that NYSED has delineated tests that may be ordered by particular medical professions.

29. Within thirty (30) days of the Effective Date, LabCorp shall submit to the OAG, for its review and comment, a written document outlining the internal process set forth in Paragraph 28.

30. Compliance:

a. Initial: LabCorp shall submit to the OAG, within sixty (60) days of the Effective Date, a detailed letter certifying and setting forth its initial compliance with this Assurance.

b. Ongoing: LabCorp shall submit to the OAG at the end of each of the first two years after the Effective Date a detailed letter certifying and setting forth its ongoing compliance with this Assurance (the “Compliance Letter”).

31. The OAG recognizes there may be changes in the future to New York State laws or regulations affecting clinical laboratory testing that may permit LabCorp to engage in conduct otherwise prohibited by this Agreement. In the event of such a change, LabCorp shall advise the OAG in writing on the change in law and its impact on the terms of this Agreement and request any appropriate change to the terms of this Agreement. The OAG shall consider LabCorp’s request in good faith and respond within 30 days. If the OAG rejects LabCorp’s request, the OAG agrees that LabCorp may commence an action in New York State Supreme Court seeking a

judicial declaration of the impact in the change in law or regulation and relief from the specific terms of this Agreement relating to the change in law or regulation.

#### **IV. CIVIL PENALTIES**

32. Within 30 days of the Effective Date, LabCorp will pay \$225,000 to the OAG as a civil penalty. Such sum shall be payable by check to “State of New York Department of Law.”

#### **V. LIQUIDATED DAMAGES**

33. If LabCorp violates any provision of this Assurance, the OAG may elect to demand that LabCorp pay liquidated damages of \$1,000 per violation for such non-compliance. Before liquidated damages may be imposed, the OAG shall give LabCorp written notice that LabCorp may be subject to liquidated damages under this Paragraph. In the event that LabCorp does not cure the violation within ten (10) days of receipt of the OAG’s written notice, the OAG may impose liquidated damages pursuant to this Paragraph. The damages period shall commence on the date that LabCorp receives the OAG’s written notice and end on the date that LabCorp cures the violation or provides the requested information.

#### **VI. GENERAL PROVISIONS**

33. LabCorp’s Representations: The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to the OAG by LabCorp and its counsel and the OAG’s own factual investigation as set forth in the above Findings. To the extent that any material representations are later found to be inaccurate or misleading, this Assurance is voidable by the OAG in its sole discretion.

34. Communications: All communications, reports, correspondence, and payments that LabCorp submits to the OAG concerning this Assurance or any related issues is to be sent to the attention of the person identified below:

Michael D. Reisman, Esq.  
Assistant Attorney General  
Health Care Bureau  
Office of the New York State Attorney General  
120 Broadway  
New York, New York 10271

35. Receipt by the OAG of materials referenced in this Assurance, with or without comment, shall not be deemed or construed as approval by the OAG of any of the materials, and LabCorp shall not make any representations to the contrary.

36. All notices, correspondence, and requests to LabCorp shall be directed as follows:

General Counsel  
Laboratory Corporation of America  
531 S. Spring St.  
Burlington, NC 27215

37. Valid Grounds and Waiver: LabCorp hereby accepts the terms and conditions of this Assurance and waives any rights to challenge it in a proceeding under Article 78 of the Civil Practice Law and Rules or in any other action or proceeding.

38. No Deprivation of the Public's Rights: Nothing herein shall be construed to deprive any member or other person or entity of any private right under law or equity.

39. No Blanket Approval by the Attorney General of LabCorp's Practices: Acceptance of this Assurance by the OAG shall not be deemed or construed as approval by the OAG of any of LabCorp's acts or practices, or those of its agents or assigns, and none of them shall make any representation to the contrary.

40. Monitoring by the OAG: To the extent not already provided under this Assurance, LabCorp shall, upon request by the OAG, provide all documentation and information necessary for the OAG to verify compliance with this Assurance. LabCorp may request an extension of particular deadlines under this Assurance, but OAG need not grant any such request.

This Assurance does not in any way limit the OAG's right to obtain, by subpoena or by any other means permitted by law, documents, testimony, or other information.

41. No Limitation on the Attorney General's Authority: Nothing in this Assurance in any way limits the OAG's ability to investigate or take other action with respect to any non-compliance at any time by LabCorp with respect to this Assurance, or LabCorp's non-compliance with any applicable law with respect to any matters.

42. No Undercutting of Assurance: LabCorp shall not take any action or make any statement denying, directly or indirectly, the propriety of this Assurance or expressing the view that this Assurance is without factual basis. Nothing in this paragraph affects LabCorp's: (a) testimonial obligations, or (b) right to take legal or factual positions in defense of litigation or other legal proceedings to which the OAG is not a party. This Assurance is not intended for use by any third party in any other proceeding.

43. Under Executive Law Section 63(15), evidence of a violation of this Assurance shall constitute prima facie proof of a violation of the applicable law in any action or proceeding thereafter commenced by the OAG.

44. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

45. If a court of competent jurisdiction determines that LabCorp has breached this Assurance, LabCorp shall pay to the OAG the cost, if any, of such determination and of enforcing this Assurance, including, without limitation, legal fees, expenses, and court costs.

46. If the Assurance is voided or breached, LabCorp agrees that any statute of limitations or other time-related defenses applicable to the subject of the Assurance and any claims arising from or relating thereto are tolled from and after the date of this Assurance. In the

event the Assurance is voided or breached, LabCorp expressly agrees and acknowledges that this Assurance shall in no way bar or otherwise preclude the OAG from commencing, conducting or prosecuting any investigation, action or proceeding, however denominated, related to the Assurance, against LabCorp, or from using in any way any statements, documents or other materials produced or provided by LabCorp prior to or after the date of this Assurance.

48. None of the parties shall be considered to be the drafter of this Assurance or any provision for the purpose of any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter hereof. This Assurance was drafted with substantial input by all parties and their counsel, and no reliance was placed on any representation other than those contained in this Assurance.

49. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held to be invalid, illegal, or unenforceable in any respect, in the sole discretion of the OAG such invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.

50. This Assurance contains an entire, complete, and integrated statement of each and every term and provision agreed to by and among the parties, and the Assurance is not subject to any condition not provided for herein. This Assurance supersedes any prior agreements or understandings, whether written or oral, between and among the OAG and LabCorp regarding the subject matter of this Assurance.

51. This Assurance may not be amended or modified except in an instrument in writing signed on behalf of all the parties to this Assurance.

52. The division of this Assurance into sections and subsections and the use of captions and headings in connection herewith are solely for convenience and shall have no legal

effect in construing the provisions of this Assurance.

53. Binding Effect: This Assurance is binding on and inures to the benefit of the parties to this Assurance and their respective successors and assigns, provided that no party, other than the OAG, may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without prior written consent of the OAG. "Successors" includes any entity which acquires the assets of LabCorp or otherwise assumes some or all of LabCorp's current or future business.

54. Effective Date: This Assurance is effective on the date that it is signed by the Attorney General or his authorized representative (the "Effective Date"), and the document may be executed in counterparts, which shall all be deemed an original for all purposes.

**AGREED TO BY THE PARTIES:**

Dated: Burlington, NC  
December 22, 2015

**LABORATORY CORPORATION OF  
AMERICA**

By: 

F. SAMUEL EBERTS III  
SENIOR VICE PRESIDENT AND  
CHIEF LEGAL OFFICER

App'd As To Form  
LAW DEPT.  
By KWK

Dated: New York, New York  
December 29, 2015

**ERIC T. SCHNEIDERMAN**  
Attorney General of the State of New York

LISA LANDAU  
Health Care Bureau Chief

By:   
MICHAEL D. REISMAN  
ELIZABETH CHESLER  
Assistant Attorneys General  
Health Care Bureau