ATTORNEY GENERAL OF THE STATE OF NEW YORK

In the Matter of

Direct Laboratory Services, LLC

Assurance No.: 15-168

ASSURANCE OF DISCONTINUANCE
UNDER EXECUTIVE LAW
SECTION 63, SUBDIVISION 15

Pursuant to the provisions of Section 63(12) of the Executive Law, New York Education Law Section 6515, and Article 22-A of the General Business Law, Eric T. Schneiderman, Attorney General of the State of New York, caused an inquiry to be made into certain business practices of Direct Laboratory Services, LLC ("DirectLabs"). Based upon that inquiry, the Office of the Attorney General ("the OAG") has made the following findings, and DirectLabs has agreed to modify its business practices and comply with the following provisions of this Assurance of Discontinuance ("Assurance").

I. BACKGROUND

1. DirectLabs is a limited liability company established in Louisiana, with its principal place of business at 4040 Florida Street, Suite 101, Mandeville, Louisiana, 70448.

2. DirectLabs, which is neither a laboratory nor a medical provider, offers consumers nationwide "direct access" – i.e., access without a physician's involvement – to over 250 clinical laboratory tests. It does this by selling doctors' orders for the laboratory testing available through its website and partnering with Laboratory Corporation of America ("LabCorp") to have those orders accepted at LabCorp patient service centers. These tests

range from basic cholesterol level testing to screening for serious diseases, such as celiac disease and various cancers.

3. From September 2012 until March 2015, DirectLabs operated a separate online and telephone service (called "DirectLabs Access") that enabled New Yorkers to access this diagnostic clinical laboratory testing without consulting a licensed physician or other authorized provider.[1]

4. However, New York law generally prohibits such "direct access testing," and instead requires that laboratory tests be performed only at the request of licensed medical providers within their scope of practice.

II. THE OAG'S INVESTIGATION

5. In five different transactions in late 2014 and early 2015, a female investigator with the OAG purchased requisitions for the following seven tests through DirectLabs Access:

- Cancer Antigen (CA) 27.29 – a test that may indicate a recurrence of breast cancer;
- Creatine Kinase, Total (CK), Serum – a test for non-specific muscle inflammation;
- Hepatitis B Surface, Ag – one of several tests for Hepatitis B;
- Rheumatoid Arthritis (RA) Factor – a test to help diagnose Rheumatoid Arthritis;
- PSA (Prostate Specific Antigen) – a test, almost exclusively for *males*, that may help diagnose prostate cancer;

[1] DirectLabs operated DirectLabs Access for New York, New Jersey and Rhode Island consumers until March 2015, when it closed as a result of the OAG's investigation. DirectLabs continues to operate in other states. Unless otherwise stated, all references to "DirectLabs" in this Assurance refer to this separate service for New York consumers.

- Tacrolimus (FK506) – a test to measure levels of tacrolimus, an immunosuppressive drug mainly used after organ transplants; and
- Lyme Disease, Serum, Western Blot – a test that can help diagnose Lyme disease.

6. Under New York law, laboratories may only perform these tests at the request of a licensed provider, but the investigator was never examined by a licensed health care provider in connection with these tests. Moreover, the practitioner whose name appeared on the requisitions (and who was retained by DirectLabs to "authorize" the laboratory tests purchased by consumers) was a chiropractor, and therefore could not legally order four of these tests: Cancer Antigen 27.29, Rheumatoid Arthritis Factor, Prostate Specific Antigen, and Tacrolimus.

7. The investigator intentionally purchased tests that, when performed without a health care provider's involvement, may disserve consumers. For example, the CA 27.29 test was described on DirectLabs' website as a way to evaluate possible progression of breast cancer, but this test is generally regarded as a poor clinical marker of breast cancer and is not recommended for routine surveillance of patients with breast cancer.[2]

8. Further, several of the tests available through DirectLabs are not specific enough to any particular disease to be of any independent utility, such as Creatine Kinase testing, which tests for muscle inflammation and damage. Given the non-specific nature of the test and the wide range of uses, an abnormal result could mean, depending on the individual's other clinical

[2] The Mayo Clinic cautions that: "The use of CA 27.29 has not been demonstrated to provide clinical benefit to these patients, which has led some Mayo clinical investigators to conclude there is insufficient justification for routine clinical use of this new marker," and "[m]easurement of CA 27.29 is not useful to screen women for carcinoma of the breast." Mayo Clinic, *Breast Carcinoma-Associated Antigen (CA 27.29), Serum*, http://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/200814 (last visited September 29, 2015). Similarly, the American Society of Clinical Oncology's clinical practice guideline concerning the follow-up and management of patients with breast cancer specifically states that "[t]he use of . . . CA 27.29 is not recommended for routine surveillance of patients with breast cancer after primary therapy." American Society of Clinical Oncology, *Breast cancer follow-up and management after primary treatment: American Society of Clinical Oncology clinical practice guideline update, available at* http://www.guideline.gov/content.aspx?id=38701.

symptoms and physical condition, absolutely nothing of clinical significance, to a range of extremely serious medical conditions such as muscular dystrophy or a recent myocardial infarction (i.e., heart attack).[3]

9. New York's prohibition of "direct access testing" rests upon the premise that licensed medical practitioners are uniquely qualified 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 combined with the complete medical assessment of the patient are likely to reflect a false-positive or false-negative (i.e., the patient is likely to have the condition tested despite testing negative, or the patient is unlikely to have the condition tested despite testing positive). In other words, physician oversight and involvement protect patients against unnecessary testing and ensure that the test results are properly understood and utilized.

10. 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 – endanger not only the health of the individual tested, but also the health of those around them.

11. From September 2012 through March 2015, approximately 1,100 New Yorkers purchased diagnostic tests through DirectLabs, some of which cost hundreds of dollars. These tests may have been of little or no utility for any number of reasons, including that the tests were not medically appropriate for the consumer, or that the test results did not, in isolation, actually reflect that individual's likelihood of having the condition tested for.

[3] See Mayo Clinic, Creatine Kinase (CK), Serum, http://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8336 (last visited September 29, 2015).

12. In sum, DirectLabs' practices eliminated the critical gatekeeping function that medical providers play in overseeing patient health, including avoiding unnecessary, inappropriate and/or improper laboratory testing, and in doing so led New Yorkers to spend money on tests that may not provide any useful information about their medical condition and, worse still, could lead to inaccurate conclusions about of the state of consumers' health.

III. THE OAG'S FINDINGS

A. DirectLabs Sold Clinical Laboratory Requisitions to Consumers

i. Overview of DirectLabs' Business Model

13. DirectLabs never applied to the New York Department of State for authority to do business in New York State. Nonetheless, DirectLabs operated a website and a telephone service through which New Yorkers could order laboratory tests without having to consult a physician.

14. DirectLabs is not itself a laboratory and does not perform any testing. It was able to offer this service by contracting with LabCorp, such that LabCorp provided DirectLabs with access to an electronic data interface that enabled DirectLabs to: (a) generate requisitions for laboratory testing that LabCorp would accept at its patient service centers, and (b) receive the results of that testing so they could be provided to DirectLabs' customers.

15. Therefore, rather than actually performing laboratory testing, DirectLabs facilitated access to such testing at licensed laboratories – without a health care practitioner's involvement – by automatically generating requisition forms with a licensed chiropractor's name that consumers could take to a LabCorp patient service center to have the testing performed at reduced prices negotiated between LabCorp and DirectLabs.

16. DirectLabs offered New Yorkers over 250 different tests and testing packages, 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).[4] Consumers could search for tests by performing a word search or by browsing through the tests alphabetically or by category, such as by "autoimmune disorders," "autism," "blood disorders," "cancer," "food sensitivities," and "liver." Each test included the brief description of the test, the "retail" price for the test, and DirectLabs' lower price. Consumers could also view a "sample report" for the test that shows the format for reporting the results of that testing.

17. After selecting the desired tests, consumers could proceed to check out. Upon checking out, DirectLabs charged a $24 "Access Portal Charge." DirectLabs then sent consumers a requisition form for the selected tests that the consumer could bring to a LabCorp patient service center for the testing to be performed. Consumers would then pay LabCorp the price of the tests, as listed on the DirectLabs website (anywhere from $12 to over $5,000).

18. DirectLabs' website urges individuals – even those who feel healthy – to nonetheless undergo clinical laboratory testing as a way to screen for serious medical conditions before they would otherwise be detected. Its NY-targeted homepage stated: "A simple wellness blood test could save your life!" and "With a $24 access fee, we help put your health in your hands. Early detection and prevention are vitally important to your health."

19. DirectLabs' Frequently Asked Questions also urges consumers to undergo testing even if they feel healthy:

[4] 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.

Question: "I feel healthy, so why should I get tested?"

Answer: "A serious medical condition such as heart disease, prostate cancer or diabetes can exist without noticeable symptoms for up to two years. Early detection is your best defense. A simple blood test can increase your chances of identifying potential medical conditions, and establish a baseline of your normal ranges from which future tests can be monitored."

20. Instead of ensuring that a licensed physician, based on an examination of his or her patients, requested the laboratory tests for which it issued requisitions, DirectLabs contracted with a New York-licensed chiropractor whose sole function was to provide "prescriptive and clinical authority" for DirectLabs-issued requisitions in exchange for $1 per requisition (or a minimum of $100/month). This chiropractor never met or spoke with any of the approximately 1,100 consumers whose laboratory tests he authorized. When the chiropractor received a critical alert in regard to laboratory work for a DirectLabs consumer that was out of the norm, he was told by DirectLabs not to be concerned because DirectLabs would itself contact the consumer. DirectLabs ultimately generated more than 130 clinical laboratory tests for consumers that chiropractors are not legally authorized to order.

21. During the two and a half years it conducted business in New York, DirectLabs generated approximately $40,000 in revenues from issuing requisitions to New York consumers through the "Access Portal Charges."

ii. DirectLabs Offered and Sold Laboratory Orders Without a Medical Provider's Consultation

22. DirectLabs clearly articulated that it was offering New Yorkers the ability to undergo laboratory testing without having to visit or otherwise consult a physician in order to get the necessary paperwork. For $24, DirectLabs would sell consumers a doctor's order for any laboratory test it offered.

23. DirectLabs' website prominently states on its main homepage: "Your Doctor's Orders Not Necessary," and its New York-targeted homepage confirmed that consumers did not need to see their healthcare provider to purchase the tests, stating: "Direct access testing allows greater participation in one's own healthcare. Your healthcare provider can refer you to [DirectLabs], but it's not a requirement."

24. DirectLabs' website further stated: "Because [New York, New Jersey, and Rhode Island] require that their residents pay the lab directly for all lab tests, DirectLabs has created a program whereby you order the lab blood tests you want and we provide you a requisition (doctor's order) to take to the lab for a small access fee." (emphasis added).

25. Its website specifically advertised that upon payment of a $24 "Access Portal Charge," DirectLabs would generate a doctor's order for the laboratory testing:

> This [$24] access fee allows us to provide our customers with direct access to laboratory testing. Patient service center's [sic] require a requisition (doctor's order) listing the lab tests that will be drawn before a customer can be served, much like a prescription for medicine. The access fee provides you with a requisition listing the lab tests you wish to purchase.

(emphasis added).

26. Consumers also received, *via* email, an information sheet that they were instructed to present to the phlebotomist, that clearly stated the requisition was from DirectLabs (and not a licensed medical provider):

> This customer has a COR **requisition from Direct Laboratory Services, LLC** – LabCorp account number 17123875. Please make sure this order is placed on this account. The fee schedule for this account is based on LabCorp's EasyPay Fee Schedule.

(emphasis added).

IV. RELEVANT NEW YORK STATE LAW

27. 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).

28. New York General Business Law prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service" in New York State, as well as "false advertising in the conduct of any business," and authorizes the OAG to enjoin any such practices. N.Y. Gen. Bus. Law §§ 349 and 350.

A. New York Law Governing Clinical Laboratory Testing

29. As a general matter, a clinical laboratory in New York may only examine specimens "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. § 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")). [5]

30. Pursuant to the "Guidelines for Clinical Laboratory Business Model Compliance," of the Wadsworth Center, New York State's Public Health Laboratory, 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."[6]

31. The Wadsworth Center's Guidelines define "substantially and meaningfully involved" as the Department of Health's "expectation for practitioner involvement with the

[5] A limited exception 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."

[6] Available at http://www.wadsworth.org/labcert/clep/Administrative/NYSBusinessPracticeGuidelines.pdf.

patient within a patient-physician relationship, minimally including the practitioner taking a medical history and maintaining patient-specific medical records."

32. By furnishing laboratory requisitions on demand, as set forth in Paragraphs 13 through 26, DirectLabs facilitated violations of New York State's prohibition on unauthorized clinical laboratory testing.

B. New York Law Prohibiting the Unauthorized Practice of Medicine

33. New York Education Law § 6512 prohibits the unauthorized practice of a licensed profession, including medicine, as well as holding oneself out as being able to practice a licensed profession.

34. Education Law § 6515 authorizes the Attorney General to seek injunctive relief for a violation of Title 8 of the Education Law ("The Professions"), in addition to any other remedy provided by law.

35. Writing prescriptions, including those for laboratory testing, constitutes the practice of medicine. By generating orders for clinical laboratory tests upon consumers' request, as set forth in Paragraphs 13 through 26, DirectLabs engaged in the unauthorized practice of medicine, in violation of New York Executive Law § 63(12) and New York Education Law § 6512. Further, by holding itself out as being authorized to generate laboratory orders for consumers, DirectLabs held itself out as able to practice medicine, in violation of New York Executive Law § 63(12) and New York Education Law § 6512.

NOW, WHEREAS, DirectLabs does not dispute the Attorney General's findings in Paragraphs 13 through 26 above; and

WHEREAS, New York laws restricting direct access testing, prohibiting the unauthorized practice of medicine, and prohibiting deceptive business practices and misleading

advertising, confer important consumer and public health protections; and

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

WHEREAS, DirectLabs stopped offering its services to New York State residents as of March 2015 and has already posted notices that it is no longer operating in New York State;

WHEREAS, the Attorney General is willing to accept the terms of this Assurance under Executive Law Section 63(15) and to discontinue his investigation; 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:

V. PROSPECTIVE RELIEF

36. Within three days of the Effective Date, DirectLabs shall notify LabCorp by letter that it must immediately stop accepting, and examining specimens pursuant to, DirectLabs requisitions presented by New York State residents, including all New York State residents presenting at LabCorp patient service centers located in New York State.

37. Restitution: Within thirty (30) days of the Effective Date, DirectLabs shall issue refunds to each and every New York customer for the total amount the customer paid DirectLabs in access fees for requisitions that have not yet been processed by a laboratory. DirectLabs shall track which refund payments were successfully processed by its customers and make all commercially reasonable efforts to refund all customers with unused requisitions. It is anticipated that this restitution amount will total approximately $5,500 in refunds to New York consumers. DirectLabs shall provide the OAG with written reports ninety (90) and one hundred

and eighty (180) days after the Effective Date reflecting: (a) the number of individuals sent refund checks; (b) the number of individuals who have cashed or deposited those checks; and (c) all efforts to contact individuals whose checks have not been cashed or deposited.

38. Within 30 (thirty) days of the Effective Date, DirectLabs shall implement the measures set forth below:

39. DirectLabs will wind down and cease all of its remaining business operations in the State of New York, and shall deactivate any Internet or social media site or account under its possession, custody, or control that specifically solicits New York consumers.

40. DirectLabs will post notices on all Internet or social media sites and accounts under its possession, custody, or control stating that it has ceased operations in New York and will no longer do business in New York. Such notices shall remain up for no less than six months.

41. DirectLabs' homepage will continue to prominently and permanently state that its services are not available in New York State. Prominently as used in this Paragraph means text that is at or near the top of the webpage and that is distinguishable from the surrounding text through font size, color, type, style (i.e., bold or italics), or any other special effect that serves to highlight the text in relation to its surrounding text.

42. DirectLabs will continue to permit New York consumers to access their laboratory test results for a two-year period of time, commencing upon the Effective Date of this Assurance, after which time DirectLabs will deactivate those customer accounts and destroy all health information relating to DirectLabs' New York customers in its possession, custody or control, consistent with all relevant state and federal laws.

43. DirectLabs will not conduct or operate, in New York State, any business that provides requisitions to consumers for laboratory testing. However, upon a relevant change in New York law, DirectLabs may notify the OAG of such change and request that it commence its business, which it shall conduct in accordance with applicable New York law, in particular as set forth in this Assurance.

44. DirectLabs will not, through any other means, including through its continuing website and telephone operations, provide requisitions for laboratory testing to individuals identifying as New York residents.

45. Compliance: DirectLabs shall submit to the OAG, within sixty (60) days of the Effective Date, a detailed letter certifying and setting forth its compliance with this Assurance (the "Compliance Letter"). It shall attach to this letter notices described in Paragraph 40 above.

VI. CIVIL PENALTIES

46. Within 30 days of the Effective Date, DirectLabs will pay $24,500 to the OAG as a civil penalty. Such sum shall be payable by check to "State of New York Department of Law." Within 210 days of the Effective Date, DirectLabs shall also pay to the OAG the difference between $5,472 (the total amount of potential refund payments) and the actual amount in refunds paid to DirectLabs customers pursuant to Paragraph 37 as of 180 days after the Effective Date.

VII. LIQUIDATED DAMAGES

47. If DirectLabs violates any provision of this Assurance, the OAG may elect to demand that DirectLabs pay liquidated damages of $2,000 per violation for such non-compliance. Before liquidated damages may be imposed, the OAG shall give DirectLabs written notice that DirectLabs may be subject to liquidated damages under this Paragraph. In the event that DirectLabs 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 DirectLabs receives the OAG's written notice and end on the date that DirectLabs cures the violation or provides the requested information.

VIII. GENERAL PROVISIONS

48. DirectLabs' Representations: The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to the OAG by DirectLabs 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.

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

Elizabeth Chesler, Esq.
Assistant Attorney General
Health Care Bureau
Office of the New York State Attorney General
120 Broadway
New York, New York 10271

49. 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 DirectLabs shall not make any representations to the contrary.

50. All notices, correspondence, and requests to DirectLabs shall be directed as follows:

Direct Laboratory Services, LLC
4040 Florida Street, Suite 101
Marleville, LA 70448
Attn: Leigh Wilkerson, CEO

51. Valid Grounds and Waiver: DirectLabs 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.

52. 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.

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

54. Monitoring by the OAG: To the extent not already provided under this Assurance, DirectLabs shall, upon request by the OAG, provide all documentation and information necessary for the OAG to verify compliance with this Assurance. DirectLabs 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.

55. 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 DirectLabs with respect to this Assurance, or DirectLabs' noncompliance with any applicable law with respect to any matters.

56. No Undercutting of Assurance: DirectLabs 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 DirectLabs': (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.

57. 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.

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

59. If a court of competent jurisdiction determines that DirectLabs has breached this Assurance, DirectLabs 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.

60. 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.

61. 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.

62. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by DirectLabs in agreeing to this Assurance.

63. 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 DirectLabs regarding the subject matter of this Assurance.

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

65. 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.

66. 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 DirectLabs or otherwise assumes some or all of DirectLabs' current or future business.

67. 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: Mandeville, LA ~~New York, New York~~

October 2nd, 2015

Direct Laboratory Services, LLC

By: Leigh Wilkerson

Leigh Wilkerson
Chief Executive Officer

Dated: New York, New York

October 6, 2015

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

LISA LANDAU
Bureau Chief
Health Care Bureau

By:

ELIZABETH R. CHESLER
Assistant Attorney General
Health Care Bureau