

## MATERIAL CHANGE NOTICE SUBMISSION DETAILS

MCN Number	2024-05-24-1141
OHCA Review Start Date	June 5, 2024
Anticipated date (unless tolled per regulation) by which OHCA could waive cost and market impact review	July 19, 2024
Anticipated date (unless tolled per regulation) by which OHCA could determine cost and market impact review required	August 5, 2024

## SUBMITTER

### HEALTH CARE ENTITY CONTACT FOR PUBLIC INQUIRY

Title	Vice President
First Name	John
Last Name	Treadwell
Email Address	treadwj@labcorp.com

### GENERAL

Business Name	Laboratory Corporation of America Holdings
Website	labcorp.com
Ownership Type	Corporation
Tax Status	For-profit
Federal Tax ID	13-3757370
Description of Submitting Organization	<p>Submitter is a global leader of innovative and comprehensive laboratory services that provides vital information to help doctors, hospitals, pharmaceutical companies, researchers, and patients make clear and confident decisions. Submitter provides insights and accelerates innovations to improve health and improve lives through its two business segments: Diagnostic Laboratories and Biopharma Laboratory Services.</p> <p>Submitter is an industry leader in providing a wide range of clinical lab services, including gene-based and esoteric testing, such as the types of services provided by Invitae, which is now in bankruptcy.</p> <p>Submitter is a wholly-owned subsidiary of Labcorp Holdings, Inc.</p>
Health Care Provider	Yes
For Providers: Desc. of Capacity or Patients served in California	<p>The Submitter is a national provider of clinical laboratory services. Submitter owns and operates clinical laboratories in multiple states, and specimens collected from patients in California may be sent for processing to any number of these labs, depending on the type of test ordered. Below is a list of the California-licensed clinical laboratories owned by Submitter that are located in the State of California. However, these clinical labs will not be involved in providing services related to this transaction, which involves specialized genetic testing. The services currently performed in the Invitae lab will continue to be performed in that location by Labcorp</p>

	Genetics, Inc. post-transaction.
	1. 161 Rivermouth Ln, Vallejo CA 94591
	2. 6401 Pat Ave, West Hills CA 91307
	3. 19750 S Vermont Ave, Torrance CA 90502

## LOCATIONS

Counties	All Counties
California licenses and numbers	Submitter is a national provider of clinical laboratory services, and the California Department of Public Health (DPH) requires all laboratories testing specimens from California to have a California clinical laboratory license. As such, many of Submitter's laboratories both in California and in other states have clinical laboratory licenses issued by the DPH. However, those laboratories are not involved in this transaction, which involves the performance of specialized genetic tests that will continue to be performed in the clinical laboratory currently owned by Invitae, and to be acquired by Labcorp Genetics Inc.
Other States Served	AK; AL; AR; AZ; CO; CT; DC; DE; FL; GA; HI; IA; ID; IL; IN; KS; KY; LA; MA; MD; ME; MI; MN; MO; MS; MT; NC; ND; NE; NH; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; UT; VA; VT; WA; WI; WV; WY
Other state(s) licenses and numbers	Submitter holds clinical laboratory licenses in other states but none are involved in this transaction.
Primary Languages used when providing services	English

## MATERIAL CHANGE

### ADDITIONAL ENTITIES

Business Name	Description of the Organization	Ownership Type
Invitae Corporation		Corporation

### CRITERIA

A health care entity with annual revenue, as defined in <a href="#">section 97435(d)</a> , of at least \$25 million or that owns or controls California assets of at least \$25 million, or;	Yes
A health care entity with annual revenue, as defined in <a href="#">section 97435(d)</a> , of at least \$10 million or that owns or controls California assets of at least \$10 million and is a party to a transaction with any health care entity satisfying subsection (b)(1), or	Yes

## CIRCUMSTANCES FOR FILING

The proposed fair market value of the transaction is \$25 million or more and the transaction concerns the provision of health care services.	Yes
The transaction is more likely than not to increase annual California-derived revenue of any health care entity that is a party to the transaction by either \$10 million or more or 20% or more of annual California-derived revenue at normal or stabilized levels of utilization or operation.	Yes
The transaction involves the formation of a new health care entity, affiliation, partnership, joint venture, or parent corporation for the provision of health care services in California that is projected to have at least \$25 million in California-derived annual revenue at normal or stabilized levels of utilization or operation, or transfer of control of California assets related to the provision of health care services valued at \$25 million or more.	Yes

## TRANSACTION DETAILS

Anticipated Date of Transaction Closure	7/28/2024
Description of Transaction	See attached.
Submitted to US Department of Justice or Federal Trade Commission?	Yes
Date of Submission	5/14/2024
Subject to court proceeding	Yes
Name of Court(s), case number	Inviat Corporation (25-11362) ArcherDX, LLC (24-11364) ArcherDX Clinical Services, Inc. (24-11363) Genetic Solutions LLC (24-11365) Genosity, LLC (24 11361) Ommdom Inc. (24 11366)
Description of current services provided and expected post-transaction impacts on health care services	Within California, all services are performed in San Francisco county. There are no expected post-transaction changes thereto.  Submitter performs genetic testing services. There are no expected post-transaction changes thereto.  Invitae has submitted a summary of patients currently served. There are no expected post-transaction changes thereto.  Medi-Cal and Medicare patients are currently accepted. There are no expected post-transaction changes thereto.
Prior mergers or acquisitions that: (A) involved the same or	As to Submitter: 1. Laboratory Corporation of America Holdings acquired Sequenom, Inc., which specializes in certain genetic tests for

<p>related health care services; (B) involved at least one of the entities, or their parents, subsidiaries, predecessors, or successors, in the proposed transaction; and (C) were closed in the last ten years.</p>	<p>non-invasive prenatal testing (9/17/16) 2. Labcorp acquired MNG Laboratories, which specializes in next generation sequencing and complex biochemical testing for neurology (3/1/19) 3. Labcorp acquired OmniSeq, a pioneer in solid tumor profiling that uses genetic sequencing technologies (7/20/21) 4. Labcorp acquired Personal Genome Diagnostics Inc. (PGDx), a leader in cancer genomics (2/21/22)</p> <p>As to Invitae: 1. Genosity (2021): Acquired Genosity which specializes in next-generation sequencing in oncology, enhancing Invitae's personalized oncology testing and clinical trial capabilities. 2. ArcherDX (2020): This acquisition created a leader in comprehensive cancer genetics and precision oncology, integrating ArcherDX's genomic analysis capabilities with Invitae's genetic testing services. Assets related to RUO kits (excluding PCM) were sold in 2023. 3. Jungla (2019): Invitae acquired Jungla to bolster its computational and functional genomics capabilities. This acquisition helped enhance the accuracy and scalability of Invitae's genetic variant interpretation. 4. Clear Genetics (2019): Acquired to integrate its conversational AI platform, GIA, enhancing patient communication and genetic counseling services. 5. Ommdom (2017): Acquired its CancerGene Connect, a tool that helps collect and manage family history and genetic data to streamline genetic risk assessment in oncology. 6. PatientCrossroads/AltaVoice (2016): Acquired to expand Invitae's patient-initiated information networks (PINs), facilitating better data collection and patient engagement in research."</p>
<p>Description of Potential Post Transaction Changes</p>	<p>Submitter does not currently anticipate making any ownership, governance, or operational structure changes related to the Invitae assets post-closing.</p> <p>Submitter does not currently anticipate making any material employee staffing level, job security, retraining policy, wage, benefits, working conditions, or employment protection changes related to the Invitae assets post-closing.</p> <p>Submitter does not currently anticipate making any changes to city or county contracts regarding the provision of health care services that are related to the Invitae assets post-closing.</p> <p>The parties are unaware of any potential post-transaction changes to comparable health services offered by other health care entities within 20 miles of any party location.</p>
<p>Description of the nature, scope, and dates of any pending</p>	<p>None as to Invitae. On March 28, 2024, Labcorp announced the acquisition of select assets of Bioreference's Health Diagnostics</p>

or planned material changes occurring between the Submitter and any other entity, within the 12 months following the date of the notice	business from OPKO Health. The transaction is expected to close during the second half of 2024.
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## 6. Description of Transaction

Description of the transaction

*Please Address All of the Following:*

*1. The goals of the transaction;*

**On February 13, 2024, Invitae filed for Chapter 11 bankruptcy. The goal of this transaction is for Invitae to sell its assets to pay its creditors and settle its executory debts, while maintaining patient access to Invitae's services.**

*2. A summary of the terms of the transaction;*

**The transaction is an asset sale, through which Labcorp Genetics, Inc., a newly formed entity and subsidiary of Submitter, will acquire certain assets of Invitae in accordance with Section 1.1 of the negotiated Asset Purchase Agreement and certain requirements under the Bankruptcy Code. As part of the transaction, Labcorp Genetics, Inc. committed to hiring at least 95% of Submitter's employees at compensation and benefit levels at least as favorable as those the employees receive pre-closing, as set forth in Section 6.3 of the Asset Purchase Agreement.**

*3. A statement of why the transaction is necessary or desirable;*

**This transaction is necessary because the Invitae is already in active bankruptcy proceedings and needs to sell its assets to pay its debts. An immediate sale of its assets is necessary to avoid conversion of Invitae's Chapter 11 case to a Chapter 7 liquidation. The transaction is essential to avoid further depletion of cash reserves, thereby threatening Invitae's ability to remain administratively solvent. Despite filing for bankruptcy, Invitae has continued to incur substantial operating losses, and burn approximately \$9-10 million per month, comprised of approximately \$4.5 million in negative operating cash flow and \$5 million in additional Chapter 11 costs.**

**The transaction is desirable because it ensures that the valuable genetic testing technologies and services developed by Invitae will continue to be available and will evolve under new ownership, thereby preserving the public benefit these services provide. By acquiring the Invitae assets, Submitter will strengthen its genetic specialty testing capabilities, especially in key complementary health areas such as oncology and rare diseases, which are aimed at enhancing patient care and providing insights into their health with improved accessibility to genetic data.**

*4. General public impact or benefits of the transaction, including quality and equity measures and impacts;*

**Invitae invested time, energy and resources into researching and developing diagnostic services that leverage the use of genetic information to allow a greater number of patients access to cutting edge medical treatment. While Invitae will cease operations, the transaction ensures that the public will continue to benefit from its innovative genetic testing and health solutions under Labcorp ownership. Submitter's commitment, under the Asset Purchase Agreement, to assume the operation of Invitae's lab and to hiring a substantial number of Invitae's employees not only helps preserve jobs, but also ensures continuity of expertise and service quality. This transition aims to maintain and enhance the availability and quality of genetic testing services for patients in California and in other states.**

**Absent the transaction, Invitae faces a significant risk of having to cease operations, an outcome that would be to the detriment of all individuals that use Invitae’s genetic testing services to better understand their susceptibility to various diseases and to make more informed decisions about their healthcare.**

*5. Narrative description of the expected competitive impacts of the transaction; and*

**The transaction is expected to enhance competition. As noted above, Invitae is in Chapter 11 bankruptcy proceedings. But for the transaction, Invitae faces a significant risk of having to cease operations altogether and to be liquidated. Under Labcorp ownership, the Invitae assets will be deployed to enable Labcorp Genetics, Inc. to compete with other genetic testing providers across the country.**

*6. Description of any actions or activities to mitigate any potential adverse impacts of the transaction on the public.*

**Submitter’s commitment, under the Asset Purchase Agreement, to hiring a substantial number of Invitae’s employees not only helps preserve jobs, but also ensures continuity of genetic testing expertise and service quality.**



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June 4, 2024

Kristen Colburn  
Senior Counsel, Health Systems Compliance  
2020 West El Camino Avenue, Suite 800  
Sacramento, CA 95833

Dear Ms. Colburn,

On behalf of Laboratory Corporation of America Holdings (“LCAH”), I am writing in response to your May 27 letter regarding the Material Change Notice Submission 2024-05-24-1141. Below, we address each item in your request.

I authorize OHCA to amend my submission on my behalf (and on behalf of LCAH) to include the additional documents and information requested by OHCA in its letter dated May 27, 2024. I certify under penalty of perjury under the laws of the State of California that the information and documents provided in the foregoing Material Change Notice are true and correct.

Please let us know if you have any questions regarding the information submitted herein.

Many thanks,

Jessica Hanna



**ITEM 1.**

**Information Requested:** General information regarding the submitter: (D) Description of organization, including but not limited to, business lines or segments, ownership type (corporation, partnership, limited liability company, etc.), governance and operational structure (including ownership of or by a health care entity). (i) For health care providers or fully integrated delivery systems, include a summary of provider type (hospital, physician group, etc.), facilities owned or operated, service lines, number of staff, geographic service area(s), and capacity (e.g., number of licensed beds) or patients served (e.g., number of patients per county) in California in the last year.

**OHCA Comment:** Please provide a summary of service lines, number of staff, and patients served by LCAH in California in the last year.

**LCAH Response:**

**1. Service lines**

LCAH is organized under two segments:

- (i) Diagnostics Laboratories (Dx), which includes routine testing and specialty/esoteric testing; and
- (ii) Biopharma Laboratory Services (BLS), consisting of Early Development Research Laboratories and Central Laboratory Services.

Information regarding each segment is provided below.

**Dx Segment:** Dx is an independent clinical laboratory business. It offers a comprehensive menu of frequently requested core testing and specialty testing through an integrated network of primary and specialty laboratories across the U.S. and Canada. Dx also provides patient access points that are located throughout the U.S. Although testing for healthcare purposes and customers who provide healthcare services represents the most significant portion of the clinical laboratory industry, clinical laboratories also perform testing for other purposes and customers, including employment and occupational testing, DNA testing to determine parentage and to assist in immigration eligibility determinations, environmental testing, wellness testing, toxicology testing, pain management testing, and medical drug monitoring. Dx offers an expansive test menu that includes a wide range of clinical, anatomic pathology, genetic and genomic tests, and regularly adds new tests and improves the methodology of existing tests to enhance patient care.

**BLS Segment:** BLS provides drug development, medical device and companion diagnostic development solutions from early-stage research to clinical development, along with support for crop protection and chemical testing, through its Early Development Research Laboratories and

Central Laboratory Services businesses. Its customers are comprised of pharmaceutical, biotechnology, medical device, and diagnostic companies across the world.

## 2. Staff

LCAH and its subsidiaries have 4,669 employees in the state of California as of May 29, 2024.

## 3. Patients in California

LCAH and its subsidiaries provided laboratory testing services to approximately 5.8 million patients in California in 2023. The number of patients by county in California is set forth in Attachment A.

### **ITEM 2.**

**Information Requested:** A description of current services provided by the health care entity and expected post-transaction impacts on health care services, which shall include, if applicable:

- A. Counties where services are currently performed and any post-transaction changes thereto;
- B. Levels and type of health care services currently offered, such as the full range of reproductive health care and sexual health care services, specialized services for LGBTQ+ populations, labor and delivery services, pediatric services, behavioral health services, cardiac services, and emergency services, and any post-transaction changes thereto;
- C. Summary that includes the number and type of patients currently served, including, but not limited to, age, gender, race, ethnicity, preferred language spoken, disability status, and payer category, and any post-transaction changes thereto;
- D. Current community needs assessments, charity care, and community benefit programs, and any post-transaction changes thereto; and
- E. Whether Medi-Cal and Medicare patients are currently accepted and any post-transaction changes thereto.

**OHCA Comment:** A description of services is generally included in Laboratory Corporation of America Holding's Form 10-K but please additionally include a description of current services that includes information from subparts (A) through (E) as well as expected post-transaction impacts on these subparts. Since the transaction will essentially expand Laboratory Corporation of America Holding's services through the acquisition, the description may identify where services will be expanded, where services will be reduced, or whether there will be no change. The summary may indicate that certain information is not collected, if applicable.

**LCAH Response:**

- A. Counties where services are currently performed and any post-transaction changes thereto. ***LCAH and its subsidiaries provide clinical lab services to patients in all California counties, and does not anticipate any changes to this as a result of the transaction.***
- B. Levels and type of health care services currently offered, such as the full range of reproductive health care and sexual health care services, specialized services for LGBTQ+ populations, labor and delivery services, pediatric services, behavioral health services, cardiac services, and emergency services, and any post-transaction changes thereto; ***LCAH and its subsidiaries provide laboratory testing services.***
- ***LCAH's frequently-ordered tests used in regular patient care include blood chemistry analyses, urinalyses, blood cell counts, thyroid tests, Pap tests, hemoglobin A1C, prostate-specific antigen (PSA), tests for sexually transmitted diseases (e.g., chlamydia, gonorrhea, trichomoniasis and human immunodeficiency (HIV), and hepatitis C (HCV)), vitamin D, microbiology cultures and procedures, and alcohol and other substance abuse tests.***
  - ***LCAH also offers specialty testing, including gene-based and esoteric testing; advanced tests that target specific diseases and use new technologies; and testing services related to anatomic pathology/oncology, cardiovascular disease, coagulation, diagnostic genetics, endocrinology, infectious disease, women's health, pharmacogenetics, parentage and donor testing, occupational testing services, medical drug monitoring services, chronic disease programs, and kidney stone prevention.***
  - ***As a result of the transaction, LCAH, through Labcorp Genetics Inc., will expand its genetic testing capabilities and does not anticipate any changes to the other services it provides.***
- C. Summary that includes the number and type of patients currently served, including, but not limited to, age, gender, race, ethnicity, preferred language spoken, disability status, and payer category, and any post-transaction changes thereto; ***See Attachment A for patients per county, patients by gender, and patient age. Information on race, ethnicity, preferred language spoken, and disability status is not tracked for all patients, unless it is clinical relevant for the tests ordered. LCAH does not anticipate any changes as a result of the transaction.***
- D. Current community needs assessments, charity care, and community benefit programs, and any post-transaction changes thereto;
- ***Through The Labcorp Charitable Foundation, a private charitable 501(c)(3) (the "Foundation") LCAH and its affiliates support the mission of bringing quality health care access to all. The Foundation has issued more than 341 grants since 2020 to, among other things, support food pantries and summer meal programs for children, provide access to health care and patient support services for the underserved, broaden access to STEM education programming, and to provide ongoing support for medical research, screenings, and programs that support a healthy lifestyle. The Foundation also matches employee donations to organizations that lead the way in health care research and in***

*equitable access to care such as the American Red Cross, United Way, American Diabetes Association, and American Heart Association.<sup>1</sup>*

- *LCAH offers financial assistance for clinical lab services to patients who qualify for it, based upon the patient's completion of LCAH's application for financial hardship program and provision of supporting documentation. Financial assistance is calculated based on the patient's family size and income as compared to federal poverty income guidelines.*
- *The Community Health Needs Assessment (CHNA) requirement is not applicable to LCAH.*
- *LCAH does not anticipate any changes to these programs in connection with the transaction.*

E. Whether Medi-Cal and Medicare patients are currently accepted and any post-transaction changes thereto. *LCAH provides services for Medi-Cal and Medicare patients and will continue to provide services to these patients post-transaction.*

### **ITEM 3.**

**Information Requested:** Description of potential post-transaction changes to:

(B) The submitter's employee staffing levels, job security, retraining policies, wages, benefits, working conditions, and/or employment protections.

**OHCA Comment:** Both parties have identified that 95% of Invitae's staff will be retained by Laboratory Corporation of America Holdings following the transaction but please provide a description of post-transaction changes to staffing levels, job security, retraining policies, wages, benefits, working conditions, and/or employment protections. It would also be helpful to submit Schedule 3.14 from the Asset Purchase Agreement regarding Employee Plans. You may request confidentiality for employee names or personal information, if needed, and/or submit a redacted copy.

**LCAH Response:**

With respect to the Invitae employees that will be retained by Labcorp Genetics, Inc., the employees will be transitioned to standard benefits available to Labcorp Genetics, Inc. employees. LCAH and its affiliates provide employment protections, wages, benefits, and working conditions in accordance with applicable California and federal law. As described in the Labcorp Code of Conduct and Ethics<sup>2</sup>, Labcorp is committed to providing equal opportunity in all aspects of employment and does not tolerate any form of unlawful discrimination, harassment or retaliation.

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<sup>1</sup> More information regarding the Foundation is available at <https://www.labcorp.com/about/our-impact/charitable-foundation>.

<sup>2</sup> Available at: <https://ir.labcorp.com/static-files/ab6a66d9-d4a8-4fb0-a6e6-ca75c3778153>.

Schedule 3.14 to the Asset Purchase Agreement is attached here at Attachment B.

**ITEM 4.**

**Information Requested:** (c) Documents to Be Submitted with Notice. Except for documents submitted pursuant to subsection (c)(1), if a submitter is submitting a document in response to either subsections (b) or (c), a submitter may reference the page number or section of that submission in response to another subsection. Submitters shall upload the following documents in machine-readable portable document format (.pdf), with sections bookmarked, as applicable: (7) Existing documentation identifying the number of patients per county or enrollees per county in the last year.

**OHCA Comment:** Please provide documentation identifying the number of patients per county in the last year for Laboratory Corporation of America Holdings.

**LCAH Response:** See Attachment A.