

MATERIAL CHANGE NOTICE SUBMISSION DETAILS

MCN Number	2024-06-14-1165
OHCA Review Start Date	7/11/24
Anticipated date (unless tolled per regulation) by which OHCA could waive cost and market impact review	8/26/24
Anticipated date (unless tolled per regulation) by which OHCA could determine cost and market impact review required	9/6/24

SUBMITTER

HEALTH CARE ENTITY CONTACT FOR PUBLIC INQUIRY

Title	CEO
First Name	Steven Craig
Last Name	Allen
Email Address	legalnotices@opko.com

GENERAL

Business Name	BioReference Health, LLC
Website	bioreference.com
Ownership Type	Limited Liability Company
Tax Status	For-profit
Federal Tax ID	22-2405059
Description of Submitting Organization	<p>BioReference is an independent clinical diagnostic specialty laboratory offering a comprehensive test menu of clinical diagnostics for blood, urine and tissue analysis. This includes hematology, clinical chemistry, immunoassay, infectious disease, serology, hormones, and toxicology assays, as well as Pap smear, anatomic pathology (biopsies) and other types of tissue analysis, as well as testing for COVID-19. BioReference has sales and marketing teams. The BioReference business includes development of oncological, urological, and women's health treatments, featuring prostate cancer testing, immunoassay platforms, and development of treatments related to chronic kidney disease, cancer treatment, diabetes, and dialysis.</p> <p>Business lines or segments: BioReference is an independent clinical specialty laboratory diagnostics business and leader in providing a range of testing, including prostate cancer and immunoassay platforms.</p> <p>Ownership type: Limited Liability Company</p> <p>Governance type and operational structure: Submitter's Certificate of Formation and organizational chart provided as exhibits.</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 testing services. Submitter operates clinical laboratories in multiple states, and specimens collected from patients in California may be sent for processing to any number of these laboratories, depending on the type of test ordered. Submitter also operates twelve patient service centers for specimen collection in California.</p> <p>Below is a list of the California-licensed clinical laboratories operated by Submitter that are located in the State of California:</p> <ol style="list-style-type: none"> 3401 Winona Ave, Unit 101, Burbank CA 91504 (Clinical Laboratory License No. CDF-00349573)
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LOCATIONS

Counties	Los Angeles
California licenses and numbers	<p>Submitter is a national provider of clinical laboratory testing 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, Submitter's laboratories both in California and in other states have clinical laboratory licenses issued by the DPH.</p> <p>Submitter's clinical laboratory in California holds California licensure and is involved in the transaction:</p> <ol style="list-style-type: none"> 3401 Winona Ave, Unit 101, Burbank CA 91504 (Clinical Laboratory License No. CDF-00349573) <p>The following clinical laboratories of Submitter in Melbourne, Florida and Houston, Texas hold California licensure and are involved in the transaction:</p> <ol style="list-style-type: none"> BioReference Laboratories - Florida Clinical Laboratory, Inc (27 E. Hibiscus Blvd., Melbourne, FL 32901) Clinical and Public Health Laboratory License (California Department of Public Health – State ID CDS-90009108) BioReference Health, LLC (8282 El Rio Street, Ste. 100, Houston, TX 77054) Clinical and Public Health Laboratory License (California Department of Public Health - State ID CDS-90005852)
Other States Served	None; 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, as required by applicable state law.
Primary Languages used when providing services	English; Spanish
Other Languages	Mandarin

MATERIAL CHANGE

ADDITIONAL ENTITIES

Business Name	Description of the Organization	Ownership Type	Additional MCN Submission
Laboratory Corporation of America Holdings ("Labcorp")	See, Labcorp Material Change Notice No. 2024-06-11-1162.	Corporation	Yes
OPKO Health, Inc. (Parent Company of Submitter)	Annual Revenue: 2021: \$10,201,045 2022: \$10,019,329 2023: \$10,185,427 Counties of Operation: Not applicable – OPKO does not have locations in CA Healthcare Type: Pharmaceutical Type of Facilities: Research, pharmaceutical development Primary Languages: English, Spanish	Corporation	No

CRITERIA

A health care entity with annual revenue, as defined in section 97435(d) , 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
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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 involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 25% or more of the total California assets of the submitter(s).	Yes

TRANSACTION DETAILS

Anticipated Date of Transaction Closure	10/1/2024
Description of Transaction	<p>The transaction is expected to provide patients, physicians and customers with greater access to Laboratory Corporation of America’s comprehensive, high-quality laboratory testing services, scientific expertise and expanded testing capabilities in key regions across the United States, especially in clinical diagnostics and women’s health. The transaction is an asset sale, through which Laboratory Corporation of America Holdings will acquire certain BioReference assets in accordance with the terms of the negotiated Asset Purchase Agreement. Labcorp will acquire BioReference’s laboratory testing businesses focused on clinical diagnostics and reproductive and women’s health across the United States outside of New York and New Jersey. The acquired assets include certain business contracts, customer accounts, owned and leased real property, inventory and supplies, service marks, and owned personal property and equipment, such as furniture, fixtures, and lab equipment. The transaction is expected to provide patients, physicians and customers with greater access to Laboratory Corporation of America’s comprehensive, high-quality laboratory testing services, scientific expertise and expanded testing capabilities in key regions across the United States, especially in clinical diagnostics and women’s health.</p> <p>For health care providers and patients, it also is expected to provide improved service and reliability, faster response times, and greater access to a robust menu of tests. Submitter anticipates Labcorp will use the BioReference assets to more effectively compete by utilizing its logistical capabilities to lower costs and deliver industry-leading service quality to patients, health care providers and customers in California. The transaction will have a positive public impact because Submitter anticipates that Labcorp will be better positioned to provide patients, customers and health care providers with superior levels of service quality and robust test offerings.</p>
Submitted to US Department of Justice or Federal Trade Commission?	Yes
Date of Submission	4/19/2024
Description of current services provided and expected post-transaction impacts on health care services	<p>(A) BioReference currently provides specimen collection services at patient service centers located in the following California counties: Fresno, Monterey, San Francisco, Alameda and Santa Clara. Diagnostics testing is performed at one of BioReference’s clinical laboratories including its clinical laboratory located in Los Angeles County. Submitter expects that Labcorp will continue to provide these services post-transaction. (See, Labcorp MCN No. 2024-06-11-1162, Item No. 9(a)(A).)</p> <p>(B) BioReference currently provides clinical laboratory testing services. BioReference’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</p>

human immunodeficiency (HIV), and hepatitis C (HCV)), vitamin D, microbiology cultures and procedures, and alcohol and other substance abuse tests. Submitter anticipates that Labcorp will continue to provide these services post-transaction. (See, Laboratory Corporation of America MCN No. 2024-06-11-1162, Item No. 9(a)(B).)

(C) See Attachment “Patient Information.” Submitter anticipates that Labcorp will continue to serve these patients post-transaction. (See, Laboratory Corporation of America MCN No. 2024-06-11-1162, Item No. 9(a)(C).)

(D) BioReference recognizes that a positive relationship with host communities is important to achieving its goals of helping to save and sustaining lives and becoming an outstanding corporate citizen. BioReference conducts business so as to contribute to the overall economic vitality of the host community by operating facilities in accordance with any and all applicable laws and by supporting and encouraging public policies and community initiatives. The Community Health Needs Assessment (CHNA) requirement is not applicable to BioReference. Submitter does not anticipate any changes will be made to BioReference’s current community needs assessments, charity care, and community benefit programs for the assets it will retain post-transaction. (See, Laboratory Corporation of America MCN No. 2024-06-11-1162, Item No. 9(a)(D).) Labcorp’s community needs assessments, charity care, and community benefit programs will govern the acquired assets post-transaction.

(E) BioReference provides clinical laboratory testing services for Medi-Cal and Medicare patients throughout the state of California. Submitter anticipates that Labcorp will continue to provide services to Medi-Cal and Medicare patients post-transaction. (See, Labcorp MCN No. 2024-06-11-1162, Item No. 9(a)(E).)

Prior mergers or acquisitions that:
(A) involved the same or 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.

Submitter has no California merger or acquisition transactions in the past ten years.

<p>Description of Potential Post Transaction Changes</p>	<p>(A) Submitter does not currently anticipate making any ownership, governance, or operational structure changes. Submitter does not anticipate that Labcorp will make any post-transaction changes related to the BioReference assets included in the transaction. (See, Laboratory Corporation of America MCN No. 2024-06-11-1162, Item No. 9(c).)</p> <p>(B) Labcorp has extended offers of employment to all 63 of Submitter’s employees in California. The majority of those offers for employment have been accepted. (See, Labcorp MCN No. 2024-06-11-1162, Item No. 9(c)(B).)</p> <p>(C) Submitter does not anticipate that Labcorp will make material post-transaction changes to city or county contracts regarding the provision of health care laboratory testing services that are related to the BioReference assets included in the transaction. (See, Labcorp MCN No. 2024-06-11-1162, Item No. 9(c)(C).)</p> <p>(D) Health care providers throughout California have a wide range of clinical laboratories from which they can order laboratory testing services. Submitter is unaware of any potential post-transaction changes to comparable health services offered by other health care entities within 20 miles of Submitter’s current locations.</p> <p>(E-F) The transaction is expected to enhance competition because BioReference anticipates its complementary assets will bolster Labcorp’s ability to provide superior service levels. Labcorp and BioReference have minimal existing competitive overlap in the geographic regions covered by the acquired assets.</p>
<p>Description of the nature, scope, and dates of any pending or planned material changes occurring between the Submitter and any other entity, within the 12 months following the date of the notice</p>	<p>None.</p>