

DIVISION OF CORPORATION FINANCE

Mail Stop 3030

February 8, 2017

<u>Via E-mail</u> Dwight H. Egan President and Chief Executive Officer Co-Diagnostics, Inc. 4049 S. Highland Drive Salt Lake City, Utah 84124

> Re: Co-Diagnostics, Inc. Draft Registration Statement on Form S-1 Submitted January 12, 2017 CIK No. 0001692415

Dear Mr. Egan:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

# Explanatory Note, page 3

1. Please revise both forms of prospectus to include disclosure about the other offering, including attendant risks. Explain how the offering taking place concurrently might affect price, demand, and other factors. Make sure that your beneficial ownership table reflects all shares that may be acquired within 60 days, even if they will be registered for resale in this offering. Also, if true, highlight that significant equity holders/creditors are seeking to sell their shares as part of your initial public offering.

### Prospectus Cover, page 4

- 2. In your next amendment, please revise to name the lead underwriters or advise. Please note that we may defer further review of the filing until the lead underwriters are named.
- 3. Please include the dealer prospectus delivery obligation on the outside back cover of the prospectus. See Item 502(b) of Regulation S-K.

# Prospectus Summary, page 8

- 4. It appears that you have not derived any revenue from sales of any product and that your licensing revenue, if any, is limited. Please revise your disclosure significantly to accurately reflect the current state of your business, and to identify all statements about what you plan for your business as anticipatory only. Your summary should make clear that you have no or limited revenues.
- 5. Revise to provide a clear indication of your business plan to achieve revenues. Your discussion should make clear (1) what product, service, license, or other technology you intend to sell, (2) what material steps are needed to achieve sales of your product, service, license, or other technology, including regulatory clearances, and (3) your anticipated capital needs to complete each step.
- 6. In this regard, please revise jargon to explain what your technology or innovation does. You state that through "mathematics" and "the power of computers" you improve molecular diagnostics, but it is unclear whether you have developed your own diagnostics tools or plan to apply some additional method to existing diagnostic test, or something else. Simply defining PCR, cooperative primers, primer dimers and CLIA, among other terms, does not clarify for a person not in your industry what your proposed product is.
- 7. Where you disclose qualitative attributes about your product, competing products, or the market in which you compete, please limit those conclusions to management's belief or provide support for your conclusions. In this regard, we note your disclosure on pages 8 and 9 regarding the "fast growing" molecular diagnostics market and disclosure stating that your product represents a "radical new advancement," a "revolutionary leap forward," and is a "fraction of the cost of" and "more accurate than" competitive products. We likewise note disclosure on page 43 stating PCR diagnostics is the "gold standard" for the amplification of DNA and on page 44 regarding the "significant advantages" that your products have over competing products.
- 8. Given your reference to the U.S. in vitro market in the fourth paragraph on page 8, please highlight in your prospectus summary that you have not yet received FDA approval to market your products in the United States.

# Implications of Being an Emerging Growth Company, page 11

9. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

# Risk Factors, page 13

10. If your anticipated products will depend upon private insurance or other third party payors, please discuss attendant risk here.

# We will need to raise additional capital . . . , page 13

11. Given your current cash balance, please clarify your disclosure here indicating your belief that existing capital resources will fund your operations for twelve months. Please also disclose the amount of additional financing necessary to continue operations for twelve months.

# Use of Proceeds, page 31

- 12. Given that you have not yet disclosed the number of shares you plan to offer as part of an over-allotment option or a bona fide estimate of the price range, please tell us how you estimated the \$10 million in net proceeds, should the underwriters exercise their over-allotment option.
- 13. Please disclose the approximate amount of proceeds you intend to use for each purpose you have listed. If any material amounts of other funds are necessary to accomplish the specified purposes, please state the amounts and sources of other such funds. See Regulation S-K Item 504 and Instruction 3 to that Item. In this regard, please specifically address any capital needs to achieve necessary regulatory clearances.

# Capitalization, page 32

14. Please revise the table to present total capitalization equal to the sum of total debt and stockholders' deficit. Cash and cash equivalents are not a component of capitalization and should not be included in total capitalization.

Management's Discussion and Analysis . . . , page 34

### Executive Overview, page 37

15. We note your disclosure regarding various subscription agreements, notes, warrants, and lines of credit. Please file as exhibits all such agreements or instruments required to be filed under Item 601(b)(4) or (10) of Regulation S-K.

# Quantitative and Qualitative Disclosures about Market Risk, page 43

16. Please reconcile the statement that features of your convertible notes and warrants are deemed to be derivatives and subject to mark-to-market accounting with the accounting actually applied in the financial statements.

# Business, page 43

### Technological and Financial Advantages, page 44

17. We note your disclosure that your test "significantly outperformed" two competitors in a recent clinical study. Please clarify whether the results of the study are published. Please also provide additional details about the conditions under which this study was conducted and discuss the objective, empirical results that support the conclusion about performance set forth in the quoted language above.

#### Current Tests, page 45

18. Please clarify in which portions of the "international market" your products are available, whether you have received regulatory approval to market your products in such countries or regions, and whether you have begun to sell your products in those markets.

#### Products, page 45

- 19. Please supplementally provide us with copies of the descriptive article and commentary from *The Journal of Molecular Diagnostics*.
- 20. Please clarify what steps are necessary for your LightPRC product to be "market-ready" by 2017.

#### Revenue Model, page 46

21. Since you do not appear to have any contractual arrangements with the "largest India distributor of diagnostics," it does not appear appropriate to highlight significant details about the market served by this company, including its customer base, or to anticipated contractual terms with this company. Please revise or advise.

22. We note from the first paragraph on page 47 that you expect to expand your revenue base in "Year 2." Please clarify in what year you expect to first begin generating revenue in India and China and what steps, including regulatory approval, are necessary before you reach revenue generation in those markets.

# Market Rollout, page 47

23. We note your disclosure in numbered paragraph 4 on page 48 regarding expanding your CE mark-certified test menu. Please clarify whether any of your products have already received CE Marking. Please also describe the types of U.S. applications involving PCR tests and commercialization that you do not believe will require FDA approval, as indicated in numbered paragraph 5.

# Intellectual Property Protections, page 48

24. Please disclose the duration of your U.S. patents. See Regulation S-K Item 101(h)(4)(vii).

Executive Compensation, page 52

25. Please file as an exhibit the 2015 Long-term Incentive Plan disclosed on page 53. See Regulation S-K Item 601(b)(10)(iii).

# Certain Relationships and Related Party Transactions, page 57

- 26. Please include the names of all related persons involved in each of the disclosed transactions. See Regulation S-K Item 404(a)(1).
- 27. Please provide the required Regulation S-K Item 404 disclosures for (1) the January 2015 stock exchange agreement with Dr. Satterfield, and (2) the May 1, 2015 amended subscription agreement with Co-Diagnostics, Ltd, or advise.
- 28. Given your payment obligations to Dr. Satterfield pursuant to the minimum monthly royalty provision of the April 18, 2014 license agreement, please clarify why you paid only \$125,000 during 2015 and whether there are outstanding amounts due under this agreement. Please also disclose the amounts paid or due under this agreement since 2015.

# Description of our Capital Stock, page 57

29. Please provide the disclosure required by Regulation S-K Item 201(a)(2) and (b)(1).

# Underwriting, page 60

30. Please clarify whether Network Securities, Inc. is serving as an underwriter for this offering, as indicated in underwriter compensation table. If so, please disclose it as such on the cover page of your prospectus. See Regulation S-K Item 501(b)(8). Please also file as an exhibit the underwriting agreement referenced in this section. See Regulation S-K Item 601(b)(1).

# Audited Financial Statements as of December 31, 2015 and 2014

# Note 1 – Description of Business, page F-7

- 31. Please disclose how you accounted for the acquisition of DNA Logix and clarify the basis in the FASB Codification for your accounting determination.
- 32. We refer to the last two paragraphs on page F-7. Please revise to remove the promotional language from these paragraphs and to only present a factual disclosure of the nature of the company's operations. Refer to FASB 275-10-50-2.

# Basis of Presentation, page F-8

33. The audit report describes the financial statements as consolidated while disclosure under Basis of Presentation describes the financial statements as combined. Please revise to resolve the inconsistency between the audit report and disclosure in the notes to financial statements.

# Note 4 - Related Party Transactions, page F-16

- 34. Please revise your disclosure to clarify how the acquisition of DNA Logix impacted the license arrangement with that entity, including the payment obligations. In that regard, the parties to the license agreement filed as Exhibit 10.2 appear to be Co-Diagnostics and DNA Logix. Accordingly, it is unclear why the license fee obligations continue subsequent to your acquisition of the licensor.
- 35. Please also expand to fully describe the payment terms of the DNA Logix license as set forth in the License Fees and Royalties section of the license agreement dated April 14, 2014 and to disclose the life of the arrangement. In this regard, it appears that the license requires substantial future payments that are not described in the notes to financial statements.

# Item 17. Undertakings, page 76

36. Please include the undertaking required by Regulation S-K Item 512(f).

You may contact Andri Carpenter at (202) 551-3645 or Gary Todd, Senior Accountant, at (202) 551-3605 if you have questions regarding comments on the financial statements and related matters. Please contact Laurie Abbott at (202) 551-8071 or me at (202) 551-3528 with any other questions.

Sincerely,

/s/ Amanda Ravitz

Amanda Ravitz Assistant Director Office of Electronics and Machinery

cc: Peter DiChiara, Esq. Carmel, Milazzo & DiChiara LLP