ASX: LDX

9 April 2026

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By email: ListingsComplianceSydney@asx.com.au
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Dear Yulia

RE: Lumos Diagnostics Holdings Limited ('LDX'): ASX Aware Letter

Lumos Diagnostics Holdings Limited (**LDX** or the **Company**) refers to ASX's letter dated 30 March 2026 (**ASX Letter**) and responds as follows, using capitalised terms as defined in the ASX Letter.

1. Does LDX consider the Announcement contained information that a reasonable person would expect to have a material effect on the price or value of its securities?

Yes.

2. If the answer to question 1 is "no", please advise the basis for that view, commenting specifically on why LDX requested a trading halt for the purposes of preparing and releasing the Announcement?

N/A.

3. When did LDX first become aware of the information referred to in question 1 above? In your answer, please provide the specific date and time.

The Company first became aware of the information in respect of the grant of the 510(k) (k260787) for FebriDx and the attaching CLIA Waiver, (the **Information**) above on Wednesday, 25 March 2026:

- at 5:54am (AEDT), where it received correspondence, comprising three separate documents, from the Food and Drug Administration (**FDA**); and
- at 7:42am (AEDT), where it received further correspondence confirming the CLIA Waiver attached to the 510(k) clearance (K260787) from the FDA.

The above correspondence from the FDA collectively comprised the Information (**FDA Correspondence**). Promptly following receipt of the FDA Correspondence, and prior to the commencement of trading on Wednesday, 25 March 2026, the Company requested a trading halt in its securities in order to fully assess the content and implication of the FDA

Correspondence – particularly to assess the implications of the 510(k) documentation and CLIA-waiver designation, including a review of any conditions, qualifications, or contingencies including, for example, the new Instructions for Use, labelling requirements and other FDA-driven amendments. A full and complete assessment of these conditions was critical to ensure the Company could provide full and complete disclosure, including verification that the FDA Correspondence fully and completely satisfied commercial milestones with BARDA and Phase Scientific (as referenced in the subsequent Announcement on MAP);

4. If LDX first became aware of the information referred to in question 1 before the date of the Announcement, did LDX make any announcement prior to that date which disclosed the information? If not, please explain why the information was not released to the market at an earlier time, commenting specifically on when you believe LDX was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps LDX took to ensure that the information was released promptly and without delay.

No, as the full and complete review of the FDA Correspondence and its commercial implications was not completed until after the closure of MAP on Thursday 26 March 2026.

For additional context, up until Friday, 27 March 2026 (being the date of the Announcement), the Company made statements in several ASX announcements on MAP updating the market as to the status of the CLIA Waiver application, notably on Friday, 27 February 2026, in the announcement titled "*Lumos Delivers Several Pivotal Milestones in 1H FY26*", the Company stated:

> *On 18 August 2025, Lumos announced the completion of the clinical study and submission of its application to the FDA for CLIA waiver classification for FebriDx®. Following feedback received from the FDA at the 90-day time frame from submission, Lumos undertook a small supplementary usability assessment, which took place over 1 day, and updated the usage instructions as recommended.*
>
> *All matters have now been addressed, and the results of the assessment have been submitted to the FDA. Through the process of FDA feedback, interactions, clarification and our submission, the Company is optimistic that the CLIA waiver process remains on track and does not expect any substantive variation to the timelines previously communicated (i.e. anticipating that a decision on CLIA waiver should be received by the end of Q1 CY26 (31 March 2026).*

We also refer to the following ASX announcements on MAP where the Company provided an update to the market as to the status of the CLIA Waiver application:

- ASX announcement titled "*1H FY26 Results Investor Presentation*" dated 3 March 2026;
- ASX announcement titled "*Appendix 4D and Half Year Report*" dated 27 February 2026;
- ASX announcement titled "*Q2 FY26 Results Investor Presentation*" dated 3 February 2026;
- ASX announcement titled "*Lumos Diagnostics Quarterly Activity Statement and Cash Flow Report*" dated 29 January 2026;
- ASX announcement titled "*Lumos Diagnostics Quarterly Activity Statement and Cash Flow Report*" dated 23 October 2025;
- ASX announcement titled "*ASX SMIDcaps 2025 Conference - Presentation"* dated 24 September 2025;
- ASX announcement titled "*FY25 Results - Investor Briefing Presentation"* dated 2 September 2025; and

- ASX announcement titled "*Lumos Diagnostics Announces CLIA Waiver Application Submission for FebriDx*®" dated 18 August 2025.

Promptly following receipt of the FDA Correspondence, the Company requested an immediate trading halt prior to market open on the morning (AEDT) of Wednesday, 25 March 2026 in order to assess the contents of the FDA Correspondence and to manage its continuous disclosure obligations.

The decision to request a trading halt was made having regard to the fact that at the time the Company received the FDA Correspondence, it was not in a position to make an immediate announcement to the market in respect of that information. Specifically, the Company determined that, prior to making any market announcement, it was necessary and appropriate to undertake a thorough internal review process of the FDA Correspondence. This process included, among other things:

- **Review of the FDA Correspondence:** The Company required sufficient time to fully review and assess the nature, scope, and potential market impact of the information the subject of the FDA Correspondence – including to assess the implications of the 510(k) documentation and CLIA-waiver designation (including any new labelling etc which could be required and which may have had implications for milestone payments and commercialisation implications immediately post announcement).

- **Assessment of applicable conditions:** The Company needed to review and consider any conditions, qualifications, or contingencies including, for example, the new Instructions for Use, labelling requirements and other FDA-driven amendments, attaching to or arising from the FDA Correspondence (as a whole), in order to ensure that any announcement made to the market was accurate, complete, and not misleading.

- **Review and approval:** Consistent with the Company's internal governance processes, the information and the proposed announcement were required to be reviewed and approved by the Company's disclosure committee before release. The FDA Correspondence was also required to be submitted to the Biomedical Advanced Research and Development Authority (**BARDA**) as the funder of the CLIA Waiver application to ensure that BARDA considered the FDA Correspondence to be adequate. These processes were considered essential to ensure that the disclosure committee was appropriately briefed, that the FDA Correspondence addressed all of the Company's and BARDA's requirements, and that all implications of the content of the FDA Correspondence had been fully and completely considered, in order to formally authorise the release of the announcement to the market.

- **Preparation of the market announcement:** Following completion of the above steps, the Company also required time to prepare an appropriate market announcement that accurately and completely disclosed all material information relating to the FDA Correspondence.

The above steps together comprise the "**Announcement Approval Process**".

The trading halt was requested as a prudent measure to ensure that trading in the Company's securities did not occur during the period in which the Company was undertaking these internal processes, and whilst price-sensitive information remained non-public.

The Company considers that the Information remained confidential and incomplete prior to:

- management representing to the Board that the Announcement Approval Process had been completed and the Lumos Disclosure Committee reviewing and agreeing the form of the Announcement, which was completed by way of a circular email at 9:21pm on Thursday 26 March 2026, after the MAP had closed; and

- the Board signing off on the final form of the Announcement at 6.30am AEDT on Friday, 27 March 2026.

Accordingly, once the Lumos Disclosure Committee approved the final form of the Announcement the Company ceased to rely on the carve-outs to immediate disclosure and submitted the Announcement via ASX Online prior to market open on Friday, 27 March 2026. The Company considers that it acted promptly and without delay following the Information ceasing to be confidential and incomplete.

5. Did LDX disclose any of the contents of the Announcement to the joint lead managers to the Placement or any parties who participated in the Placement prior to the publication of that information on MAP?

The Company had existing corporate advisory mandates with MST Financial Services Pty Ltd (AFSL 500557), Barrenjoey Markets Pty Ltd (ABN 66 636 976 059) and Foster Stockbroking Pty Ltd (AFSL 223687) (together, the **Joint Corporate Advisors**).

While the Company did not disclose the substantive contents of the draft proposed Announcement to the Joint Corporate Advisors or any other third parties, the Company during Wednesday, 25 March 2026 did disclose on a strictly confidential basis to the Joint Corporate Advisors that the Company had received the FDA Correspondence (in a summarised and incomplete form due to the entirety of the FDA correspondence still being under review by Lumos management). This resulted in confidential discussions on Wednesday, 25 March 2026 between the Company and the Joint Corporate Advisors on current market conditions and the likelihood of market appetite for a capital raise by the Company given those current and evolving geo-political, economic and market conditions.

During the afternoon of Thursday, 26 March 2026, the Company and the Joint Corporate Advisors concluded discussions relating to market conditions; the potential quantum and pricing of a capital raising and a form of the capital raising deal sheet was proposed (**Deal Sheet**), specifically for sophisticated and professional investors who were capable of assessing the investment opportunity, noting that they did not have the full and complete information.

The Company considers that both the Deal Sheet and the associated confidential **Bloomberg Message** by one of the Joint Corporate Advisors were communicated in a manner consistent with ASX's guidance on confidential soundings (set out in paragraph 5.8 of Guidance Note 8).

The Deal Sheet and Bloomberg Message were accompanied by a draft Investor Presentation, which Investor Presentation was released on the ASX Markets Announcement Platform (**MAP**) immediately following the release of the Announcement. Prior to the release on MAP, the Company was continuing to work promptly and without delay in reviewing the FDA Correspondence and undertaking the Announcement Approval Process and the Company did not consider the Information to be sufficiently complete to warrant either release to the market or disclosure to the public before that Announcement Approval Process had been completed and the Announcement had been approved by the Board in accordance with the Company's internal governance processes.

6. If the answer to question 5 is "yes", does LDX consider it complied with Listing Rule 15.7? If so, please explain the basis for that view.

The Company considers it has complied with Listing Rule 15.7 on the basis that:

- the Company received the FDA Correspondence on the morning of Wednesday 25th March 2026 prior to market open, and immediately sought a trading halt, whilst the Company undertook a regulatory review of the FDA Correspondence to establish the full and complete impact of the contents of the FDA Correspondence;

- The review of the FDA Correspondence was necessary to assess the implications of the 510(k) documentation and CLIA-waiver designation, including a review of any conditions, qualifications, or contingencies including, for example, the new Instructions

for Use, labelling requirements and other FDA-driven amendments. A full and complete assessment of these conditions was critical to ensure the Company could provide full and complete disclosure, including verification that the FDA Correspondence fully and completely satisfied commercial milestones with BARDA and Phase Scientific (as referenced in the Announcement on MAP);

- the Joint Corporate Advisors were engaged on terms which included customary confidentiality obligations in favour of the Company including, amongst others, to take all reasonable steps to preserve the confidentiality of any material non-public information; and the Joint Corporate Advisors only received an update on the receipt of the FDA Correspondence not the substantive contents of the correspondence or the commercial implications which could only be established after review and determination by the Company and which was subsequently disclosed on MAP;

- prior to market open on 27 March 2026, the Company released (amongst other things) the Announcement on MAP in accordance with its continuous disclosure obligations and Listing Rule 15.7.

7. Please provide a copy of the term sheet and any other materials sent to prospective participants in the Placement (not for release to market).

Provided to ASX, as requested.

8. Please provide the list of allottees for the Placement (not for release to market).

Provided to ASX, as requested.

9. Please explain why LDX did not make any reference to raising capital in its trading halt request. In answering this question, please include a timeline from when discussions with the joint lead managers commenced through to completion of the Placement.

As stated above, the trading halt was requested by the Company in order to manage its continuous disclosure obligations in respect of the FDA Correspondence.

At the time the trading halt was requested:

- the Board had not yet resolved to proceed with the placement, and no final decision had been made in respect of the key terms of any such placement, including the quantum, pricing, or offer structure of the potential placement;

- the Company had no reasonable basis to expect the placement would proceed, particularly given global volatility and broader market uncertainty; and

- discussions with the Joint Corporate Advisors as to any potential capital raising, and the terms thereof, remained incomplete and confidential.

10. Please confirm that LDX is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.

The Company confirms it is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.

11. Please confirm that LDX's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of LDX with delegated authority from the board to respond to ASX on disclosure matters.

The Company confirms that the responses to the above question have been authorised and approved by the Board.

Yours sincerely,

Tracy Weimar
Company Secretary

Lumos Diagnostics Holdings Limited

30 March 2026

Ms Tracy Weimar
Company Secretary
Lumos Diagnostics Holdings Limited
Suite 2 Level 11 385 Bourke Street
MELBOURNE VIC 3000

By email

Dear Ms Weimar

Lumos Diagnostics Holdings Limited ('LDX'): ASX Aware Letter

ASX refers to the following:

A. LDX's 'Request for Trading Halt' released on the ASX Market Announcements Platform ('**MAP**') on 25 March 2026 disclosing the following:

The trading halt is requested pending an announcement by the Company to the market in relation to an update on the FDA response to the FebriDx CLIA waiver application (stated purpose).

B. LDX's announcement titled 'US FDA Grants CLIA Waiver for FebriDx' (the '**Announcement**'), released on MAP on 27 March 2026, which stated (relevantly):

The US FDA has granted a Clinical Laboratory Improvement Amendments (CLIA) waiver for Lumos Diagnostics' (ASX:LDX, "Lumos" or "the Company") flagship point of-care test, FebriDx®, following its 510(k) clearance [K260787].

C. LDX's announcement titled 'Lumos completes $20m placement and launches SPP' (the '**Placement**'), released on MAP on 27 March 2026 which stated (relevantly):

Lumos Diagnostics Holdings Limited (ASX: LDX, "Lumos" or the "Company"), is pleased to announce it has received firm commitments for a A$20.0 million (US$14.0 million) (before costs) institutional placement ("Placement"). Institutional demand for the placement substantially exceeded the A$20.0 million that the Company sought to raise.

In addition, the Company has received written confirmation from existing shareholders Tenmile and Ryder Capital that they will exercise at least a combined 43.9 million options that they hold, which will provide further funding to Lumos of A$3.1 million (US$2.2 million).

...

The Placement will be completed through the issue of up to 88.9 million new shares ("Placement Shares") to institutional, professional and sophisticated investors at a price of A$0.225 (22.5 cents) per Placement Share ("Placement Price") …

MST Financial Services Pty Ltd (AFSL 500557) ("MST"), Barrenjoey Markets Pty Ltd (ABN 66 636 976 059) ("Barrenjoey") & Foster Stockbroking Pty Ltd (AFSL 223687) ("FSB") acted as Joint Lead Managers and Bookrunners to the placement for which demand substantively exceeded the A$20.0 million target.

D. The change in the price of LDX's securities from $0.275 immediately prior to the release of the Announcement to a low of $0.255 following the release of the Announcement.

E. Listing Rule 3.1, which requires a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.

F. The definition of "aware" in Chapter 19 of the Listing Rules, which states that:

an entity becomes aware of information if, and as soon as, an officer of the entity (or, in the case of a trust, an officer of the responsible entity) has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity.

G. Section 4.4 in *Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B* titled "When does an entity become aware of information?"

H. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure as follows.

3.1A Listing Rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:

3.1A.1 One or more of the following 5 situations applies:

- *It would be a breach of a law to disclose the information;*
- *The information concerns an incomplete proposal or negotiation;*
- *The information comprises matters of supposition or is insufficiently definite to warrant disclosure;*
- *The information is generated for the internal management purposes of the entity; or*
- *The information is a trade secret; and*

3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and

3.1A.3 A reasonable person would not expect the information to be disclosed.

I. The concept of 'confidentiality' detailed in section 5.8 of Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. In particular, the Guidance Note states that:

Whether information has the quality of being confidential is a question of fact, not one of the intention or desire of the entity. Accordingly, even though an entity may consider information to be confidential and its disclosure to be a breach of confidence, if it is in fact disclosed by those who know it, then it is no longer a secret and it ceases to be confidential information for the purposes of this rule.

J. Listing Rule 15.7 which states (relevantly):

An entity must not release information that is for release to the market to any person until it has given the information to ASX and has received an acknowledgement that ASX has released the information to the market.

Request for information

Having regard to the above, ASX asks LDX to respond separately to each of the following questions:

1. Does LDX consider the Announcement contained information that a reasonable person would expect to have a material effect on the price or value of its securities?
2. If the answer to question 1 is "no", please advise the basis for that view, commenting specifically on why LDX requested a trading halt for the purposes of preparing and releasing the Announcement.
3. When did LDX first become aware of the information referred to in question 1 above? In your answer, please provide the specific date and time.

4. If LDX first became aware of the information referred to in question 1 before the date of the Announcement, did LDX make any announcement prior to that date which disclosed the information? If not, please explain why the information was not released to the market at an earlier time, commenting specifically on when you believe LDX was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps LDX took to ensure that the information was released promptly and without delay.
5. Did LDX disclose any of the contents of the Announcement to the joint lead managers to the Placement or any parties who participated in the Placement prior to the publication of that information on MAP?
6. If the answer to question 5 is "yes", does LDX consider it complied with Listing Rule 15.7? If so, please explain the basis for that view.
7. Please provide a copy of the term sheet and any other materials sent to prospective participants in the Placement (not for release to market).
8. Please provide the list of allottees for the Placement (not for release to market).
9. Please explain why LDX did not make any reference to raising capital in its trading halt request. In answering this question, please include a timeline from when discussions with the joint lead managers commenced through to completion of the Placement.
10. Please confirm that LDX is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.
11. Please confirm that LDX's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of LDX with delegated authority from the board to respond to ASX on disclosure matters.

When and where to send your response

This request is made under Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **9:00 AM AEDT** on **Thursday, 2 April 2026**.

You should note that if the information requested by this letter is information required to be given to ASX under Listing Rule 3.1 and it does not fall within the exceptions mentioned in Listing Rule 3.1A, LDX's obligation is to disclose the information 'immediately'. This may require the information to be disclosed before the deadline set out above and may require LDX to request a trading halt immediately if trading in LDX's securities is not already halted or suspended.

Your response should be sent by e-mail to **ListingsComplianceSydney@asx.com.au**. It should not be sent directly to the ASX Market Announcements Office. This is to allow us to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

Suspension

If you are unable to respond to this letter by the time specified above, ASX will likely suspend trading in LDX's securities under Listing Rule 17.3.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to LDX's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. It should be noted that LDX's obligation to disclose information under Listing Rule 3.1 is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

Release of correspondence between ASX and entity

We reserve the right to release all or any part of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A. The usual course is for the correspondence to be released to the market.

Regards

ASX Compliance