

Memorandum

RE: ISO 9001 and ISO 13485 Certifications and ISO 17025 Accreditation

19 November 2018

To Whom It May Concern:

This year, Pacific BioLabs will voluntarily withdraw from certification with ISO 9001:2008 and ISO 13485:2003 standards. These standards have been replaced by newer versions, which have opened up an opportunity for Pacific BioLabs. To further improve the Quality Management System and the scientific integrity of our testing, we are seeking accreditation to the ISO 17025:2017 standard, *General Requirements for the Competence of Testing and Calibration Laboratories*.

As the *Service Leader in Bioscience Testing*, we believe this accreditation is the most appropriate option available. The ISO 17025 standard contains requirements for laboratories to enable them to demonstrate they operate competently and are able to generate valid results. Laboratories that conform to this standard will also operate generally in accordance with the principles of ISO 9001.

As such, effective September 14, 2018, Pacific BioLabs no longer maintains certification to the ISO 9001:2008 standard. Pacific BioLabs remains certified to the ISO 13485:2003 standard until the expiration date of December 20, 2018. It should be noted that although certification for ISO 9001 and ISO 13485 will no longer be maintained at Pacific BioLabs, conformance to the applicable requirements for these standards will continue nonetheless. The elements of ISO 9001 and ISO 13485 pertinent to testing are incorporated in the Pacific BioLabs Quality Manual and hence are foundational to the Quality Management System.

Under Pacific BioLabs Change Control, Quality Plan #18-0113, Pacific BioLabs will obtain ISO 17025:2017 accreditation. This process is expected to be completed by the end of the first quarter of 2019.

Should you have any questions or if you would like to discuss this issue, feel free to contact me directly.

Thank you for choosing Pacific BioLabs for your testing needs. We appreciate the opportunity to collaborate.

TKC 19 Nov 2018

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