

**PRODUCT: BioProfile® FLEX2****SN: All****CIB NO: 02- 23B (Revised)****DATE: FEB 2023****BioProfile Control Level 1 Value Reassignment Lot 217848 and Lot 230838**

Dear BioProfile Customer,

A recent review of statistical data from the BioProfile FLEX2 analyzers indicates the osmolality package insert target values need to be reassigned for the following Quality Control products.

**PN 22600 BioProfile Control Level 1, Lot number 217848 and Lot number 230838**

QC Level	Analyte	New Expected Range	Old Expected Range
1	Osmolality	217 - 227 mOsm/kg H <sub>2</sub> O	215 - 225 mOsm/kg H <sub>2</sub> O

It will be necessary to update the expected control ranges in your BioProfile FLEX2 analyzer to the new expected ranges. Please disseminate the content of this bulletin to your staff and update your Quality Control ranges accordingly.

If you have any questions/concerns, or require additional information regarding this bulletin, please contact Nova Biomedical Technical Support at (800) 545-6682(USA) or (800)263-5999(Canada). For customers outside of the USA or Canada, please contact your authorized Nova Biomedical distributor.

Thank you for your continued support of Nova Biomedical products.

**Nova Biomedical, 200 Prospect Street, Waltham, MA 02454**

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