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## Assay Data Sheet - Expected Ranges BioProfile® Controls - LEVEL 8

8

Lot: 24171013

Exp: 2025-09

Instrument Instrument Appareils Strumentazione	Constituent Parameter Constituant Costituente	ExpectedRange Bereich Limites Intervallo
FLEX FLEX 2 CDV	particles/mL	$5.20 \times 10^5$ - $7.20 \times 10^5$
FAST CDV	particles/mL	$4.88 \times 10^5$ - $7.88 \times 10^5$

### Product Information

**NOVA BIOPROFILE® CONTROLS** — An assayed aqueous quality control material intended for monitoring the measurement of cell density on Nova Biomedical analyzers ONLY.

**Ingredients:** These controls are formulated from a buffered solution, each with a known quantity of polystyrene particles. The volume of each ampule is 1.7 mL.

BioProfile® Controls contain no constituents of human origin, however, good laboratory practice should be followed during handling of these materials. (REF. NCCLS DOCUMENT M29-T2)

**Storage:** Controls should be stored at 15-30°C. Each control has a lot number and expiration date printed on the label.

#### Directions for Use:

**Care must be taken to mix contents of ampule adequately as this solution contains polystyrene particles.**

If available, use a vortex to mix the ampule for 10 seconds just prior to analysis. If vortex is not available, **gently invert** the ampule 10 times just prior to analysis. During inversion, allow fluid to empty from each portion of the ampule before turning. Protecting fingers with gauze or gloves, snap open the ampule and allow the analyzer to aspirate liquid from the ampule.

**Assigned Values:** The EXPECTED RANGE for each analyte was determined at Nova by performing multiple determinations on multiple instruments using multiple runs of each level of control.

The EXPECTED RANGE indicates the maximum deviations from the mean value which may be expected under differing laboratory conditions from instruments which are operating according to specifications. Users may wish to determine EXPECTED RANGES in their own laboratory.

**Limitations:** The values appearing in the Assay Data Table are specific for instruments and reagents manufactured by Nova Biomedical.

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