

5. Proposed Device Intended Use:

N Protein Standard PY is intended to be used for the establishment of reference curves.

6. Medical device to which equivalence is claimed and comparison information.

The N Protein Standard PY is substantially equivalent in intended use to the N Protein Standard SY. Both standards are *in vitro* diagnostic reagents intended for use as a calibrator for the establishment of reference curves. The N protein Standard PY like the N Protein Standard SY is a multi-constituent standard in a blood based matrix.

The N Protein Standard PY differs from the N Protein Standard SY in that the N Protein Standard PY are intended for the calibration of coagulation assay while the N Protein Standard SY is intended for the calibration of immunology assays.

7. Proposed Device Performance Characteristics:

Precision and reproducibility:

Precision studies using one lot of N Protein Standard PY were run on the Behring Nephelometer. The %CVs ranged from 1.01 to 2.29%.

Stability

Stability was run according to in-house protocols and the control was found stable for at least 18 months lyophilized and 14 days once reconstituted.

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