

PANEL SESSION

Topic 7

ISO 17593:2007

INR Range	Allowable Difference within 90% of all results
< 2	± 0.5 INR
2.0 – 4.5	± 30%
≥ 4.5	No criteria set

FDA Proposal

INR Range	Allowable Difference within 95% of all results
< 2	± 0.4 INR
> 2.0 – 3.5	± 20%
> 3.5 – 4.5	± 20%
>4.5 or greater	± 25%

Docket No. FDA-2015-N-4462

