

***Early Phase Cell Therapy Product Development:
Potency Assays
Validation***

Cheryl Cox, MT
Manager, Experimental Cell Therapies



The Validation Plan

***Effectively establish the performance characteristics
of the procedure.***

- Number & types of samples to be studied
- Study design
- Acceptance criteria for each parameter
- Data & statistical analysis plan

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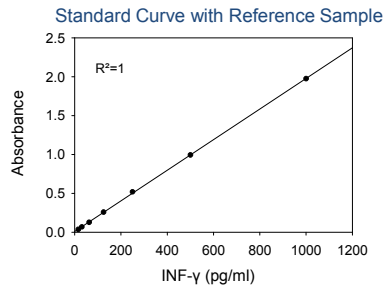
- ✓ Accuracy
- ✓ Precision
- ✓ Range
- ✓ Specificity
- ❖ Sensitivity
- ❖ Robustness

Accuracy

*The degree of agreement between the measured
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INF-γ Potency Assay Accuracy



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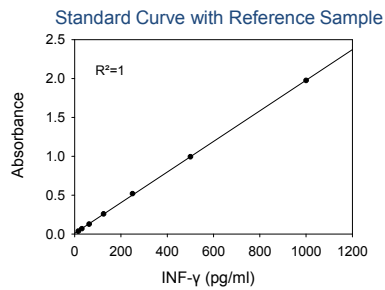


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INF- γ Potency Assay Accuracy

Standard Curve with Reference Sample

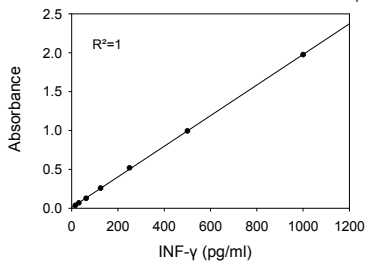
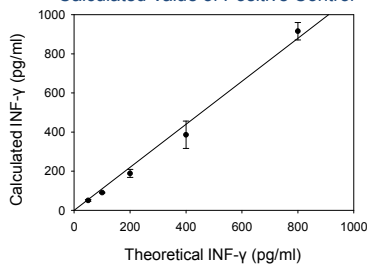


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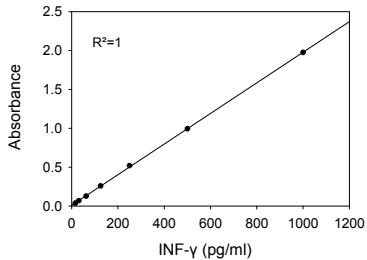


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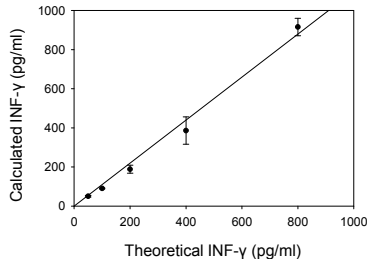


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Expected Range= 80-120% Recovery **PASS!**

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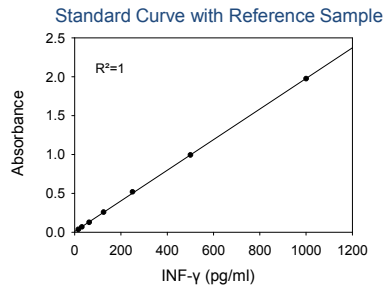
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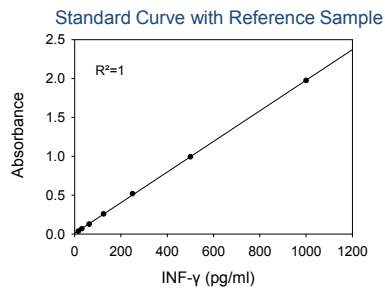


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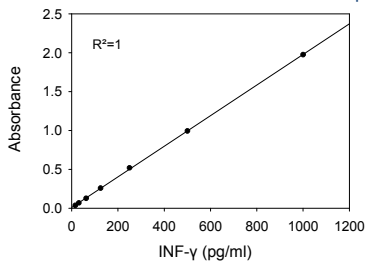
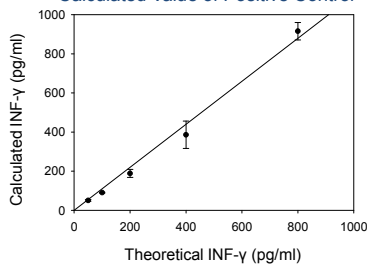


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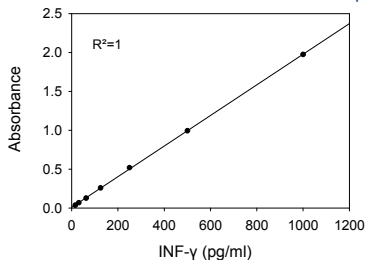


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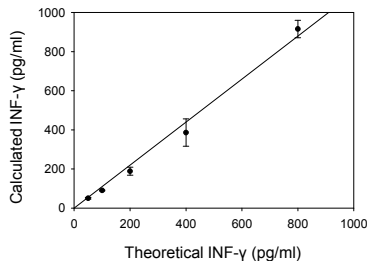


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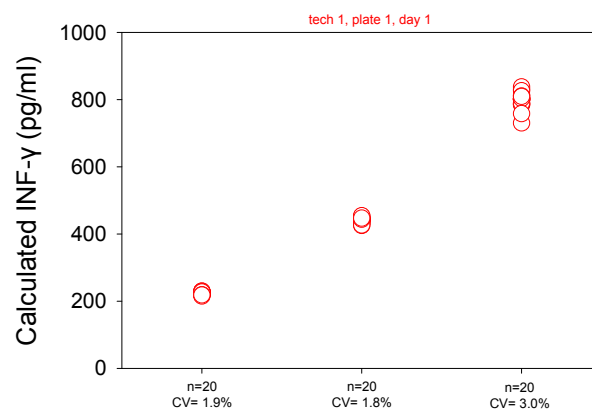
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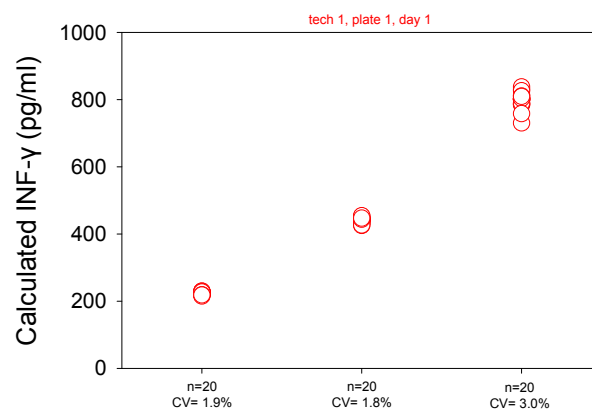
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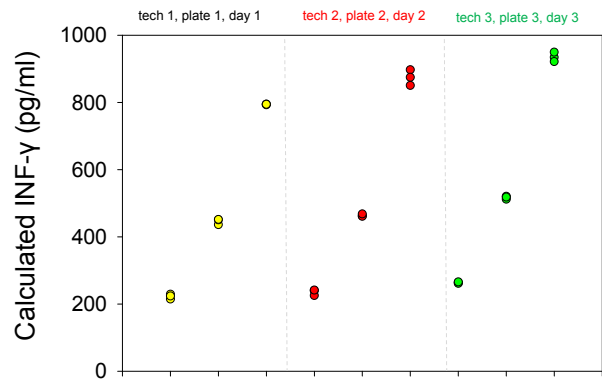
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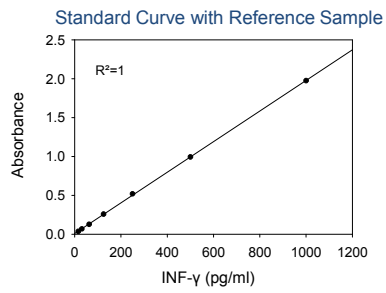
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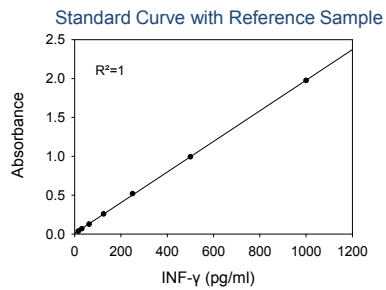


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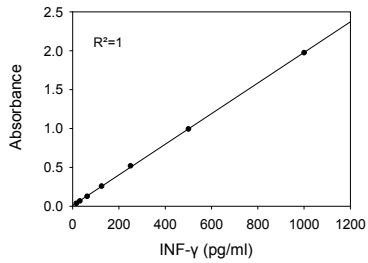
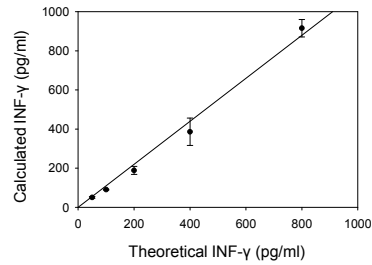


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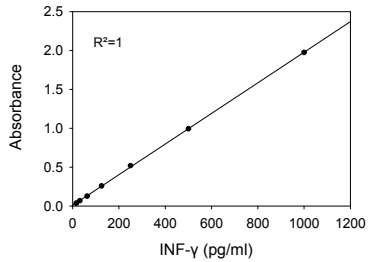


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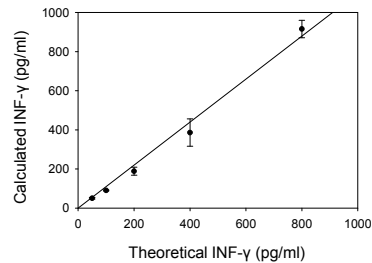


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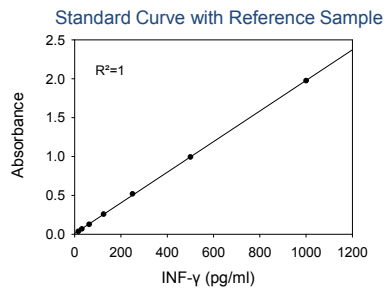
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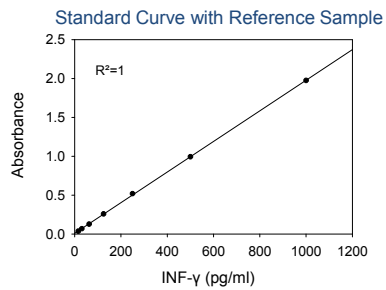


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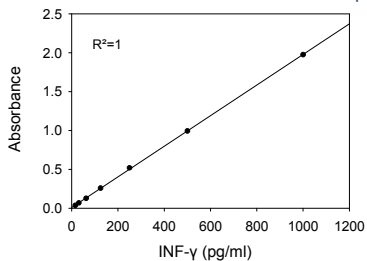
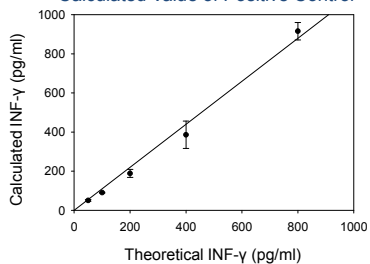


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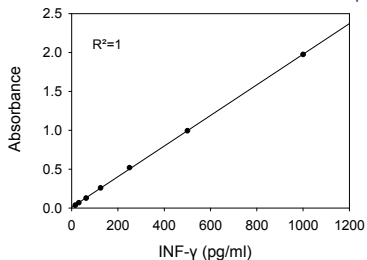


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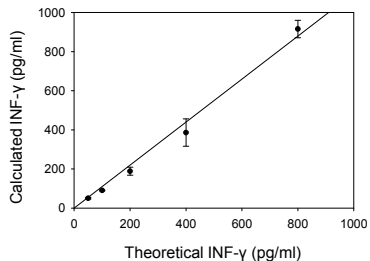


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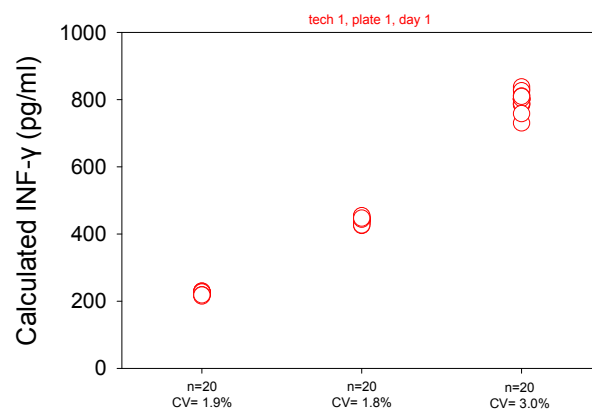
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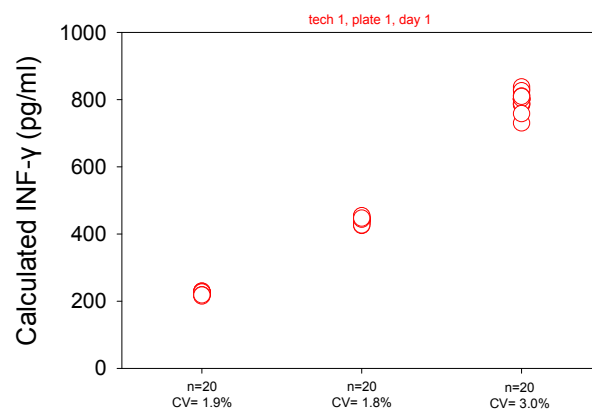
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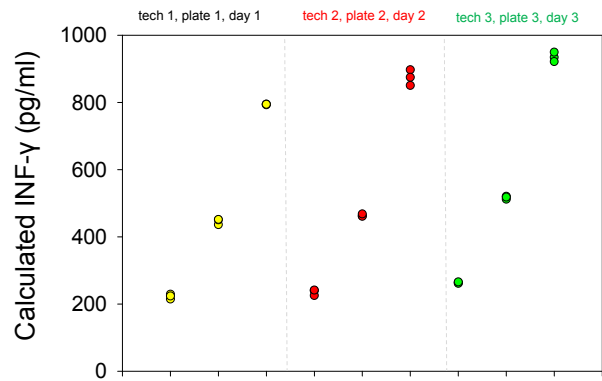
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Specificity

The degree to which only the true component is measured rather than a mistaken component (i.e., avoid false positives).

- To determine the lack of interference from components in the assay reagents or in the sample itself. Assessed by parallel dilution of the standard with and without the potentially interfering component.

Robustness

The degree to which the assay values remain unaffected by small but deliberate variations in method parameters.

- To determine the effect of pH, temperature, plate manufacturer, instruments, etc.

Lot Release Testing

TEST	Method	SPECIFICATIONS	RESULTS	Acceptable (Circle One)			Tech
Gross contamination	Gram stain	No organisms seen (NOS)		Yes	No	N/A	
Sterility	Sterility culture	No growth		Yes	No	N/A	
Endotoxin	Endosafe	<5 EU/kg		Yes	No	N/A	
Mycoplasma contamination	PCR or qPCR	Negative		Yes	No	N/A	
Viability	Dye Uptake	> 70% viable cells		Yes	No	N/A	
Cell Count	Dye Uptake	0.1 – 2 E 11 cells		Yes	No	N/A	
Interferon gamma production	ELISA	>200 pg/mL		Yes	No	N/A	

Thank You!