



## **IntelligentMDx: External Clinical Validation Studies for the BK Viral Load Assay**

External Validation Study  
BK Viral Load Assay

- **Washington University in St. Louis**
  - School of Medicine
  - Clinical Virology Laboratory
  - Dr. G. Storch
- **Compared to current in-house LightCycler quantitative assay**
- **100 Plasma and Urine samples**
  - 50 Negative
  - 50 Positive samples with a wide range of BK virus copies

# IntelligentMDx: Analytical Limit of Detection (LOD) for the BK Viral Load Assay



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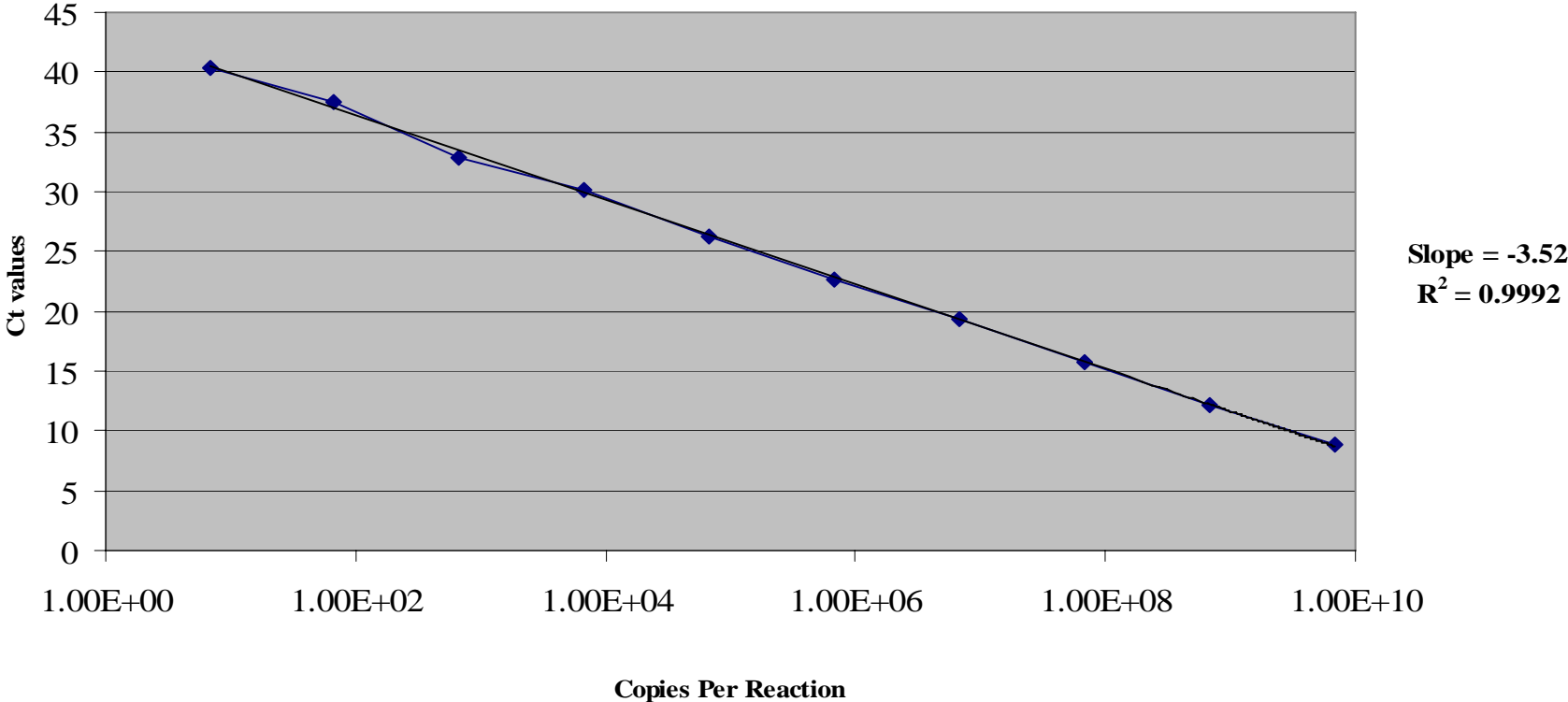
<b>BK Assay Analytical LOD</b>		
<b>BKG Plasmid</b>	<b>Copies/ Reaction</b>	<b>Percent Detected (N = 60)</b>
BK G	677	100%
BK G	268	100%
BK G	134	100%
BK G	67	98.30%
BK G	33.5	96.70%
BK G	16.8	95%
BK G	8.4	60%

# IntelligentMDx: Analytical Dynamic Range for BK Viral Load Assay



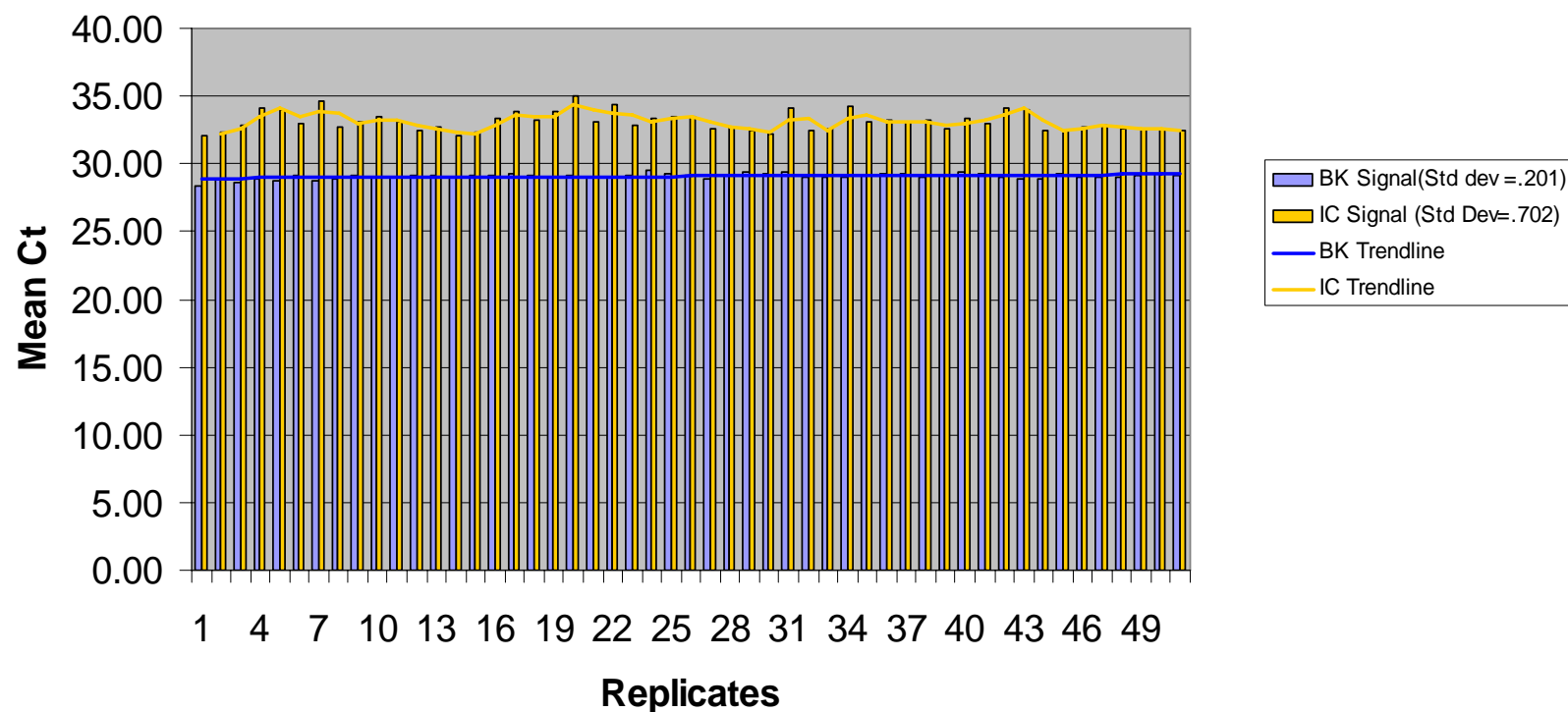
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### pBKG with Internal Control Plasmid



# IntelligentMDx: Analytical Reproducibility of the BK Viral Load Assay

## Reproducibility IntelligentMDx BK Assay



# IntelligentMDx: Predictive Value for the BK Viral Load Assay



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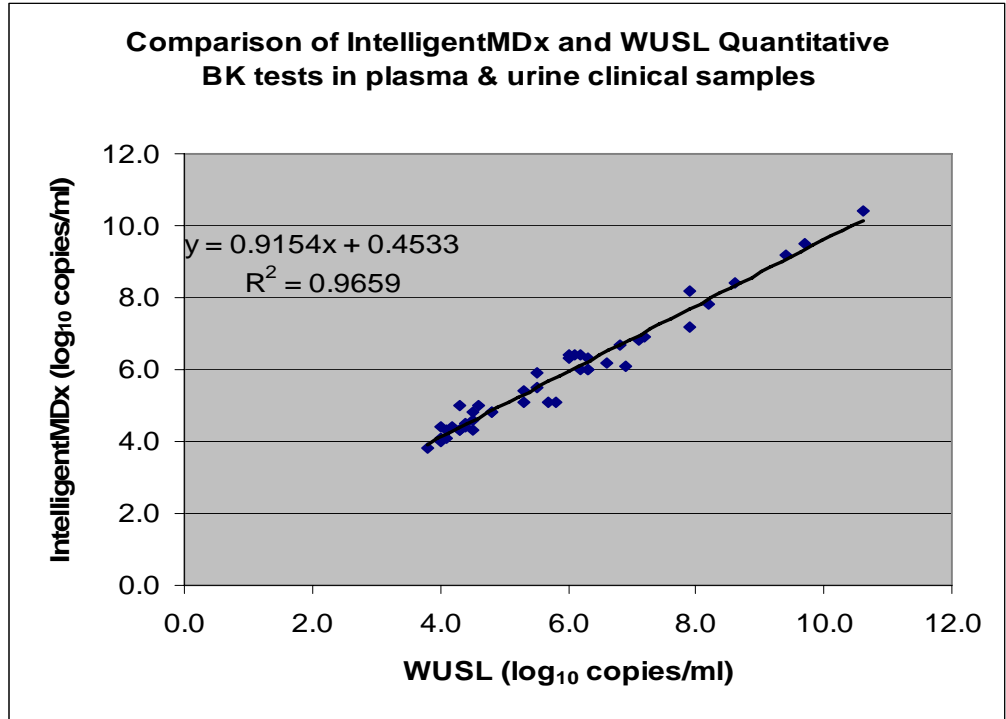
## Qualitative Results

		WUSL Nucleic Acid Based LightCycler Test		
		Positive	Negative	
IntelligentMDx BK	Positive	50	0	PPV = 100.0%
	Negative	0	50	NPV = 100.0%
		Sensitivity = 100.0%	Specificity = 100.0%	

# IntelligentMDx: Data Concordance Summary for the BK Viral Load Assay

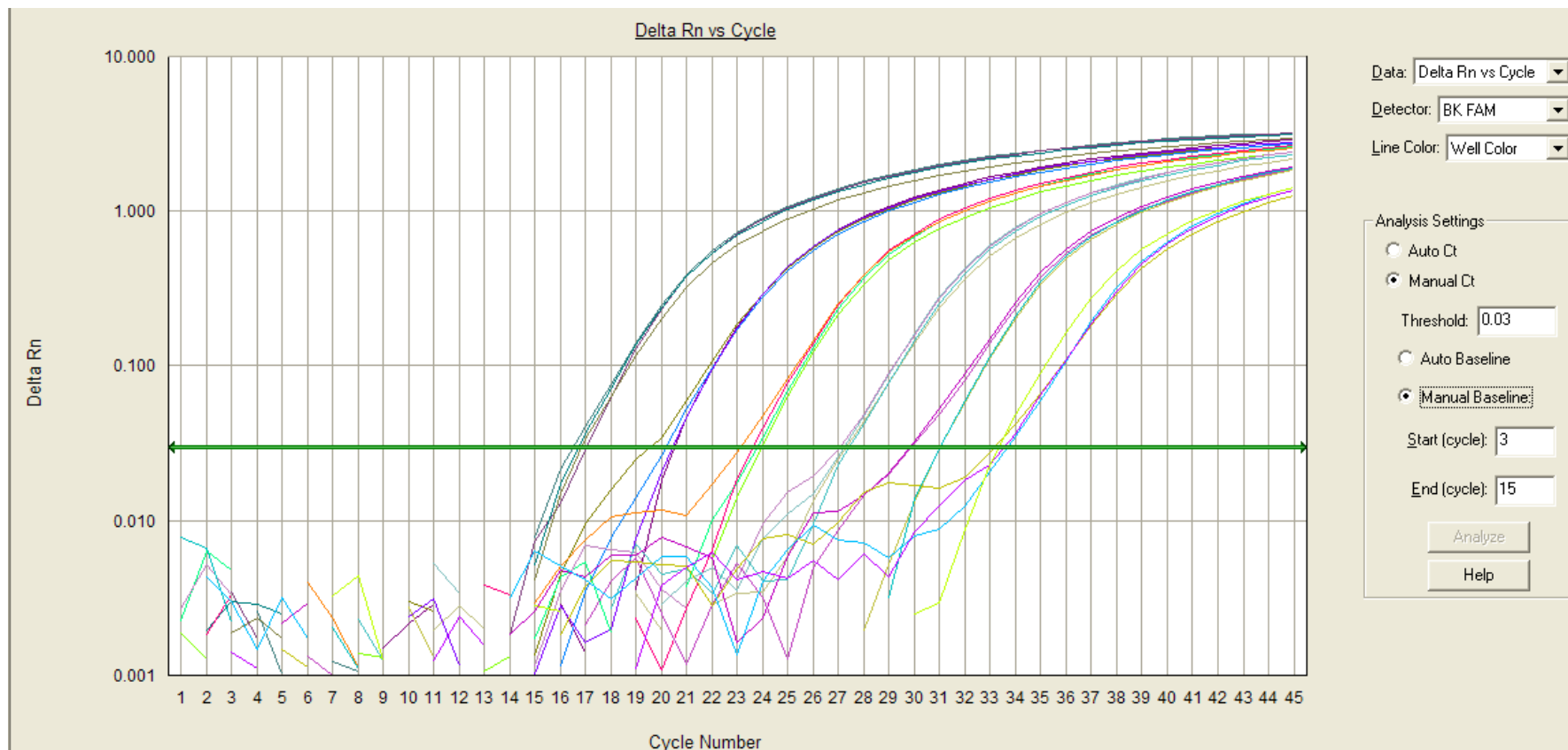


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Good concordance between IntelligentMDx and WUSL quantitative results: all within 0.5 log (<3.3 folds) except two (within 1 log).

# IntelligentMDx: Amplification Efficiency of the BK Viral Load Assay



# IntelligentMDx: Analytical Performance Summary of the BK Viral Load Assay



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- Limit of Detection - 16 copies/input
- Linear Range - Eight logs
- Precision -  $< 0.20$  (Total StDev)
- Amplification Efficiency -  $\geq 98\%$
- Genotyping Specificity - Designed to Detect all subgroups (I-IV)
- Interference - No cross reactivity