

### TECHNICAL NOTE # 10-004

RE: INTROL® CF Panel I Control v.02 (p/n: G106ac)  
ASSAY: Luminex xTAG™ Cystic Fibrosis 39 Kit v2 (IVD)  
DATE: 03/29/19

Below is a table indicating the expected calls for the INTROL® CF Panel I Control v.02 on the Luminex xTAG™ Cystic Fibrosis 39 Kit v2 (IVD)

Variation	Bottle a Call	Bottle b Call	Bottle c Call
G85E	WT	Mu D	WT
394delTT	WT	WT	HET
R117H	WT	WT	HET
Y122X	WT	WT	WT
621+1G>T	WT	Mu D	WT
711+1G>T	WT	Mu D	WT
1078delT	WT	Mu D	WT
R334W	WT	Mu D	WT
R347P	WT	Mu D	Wt D
R347H	WT	NS <sup>5</sup>	HET
A455E	WT	Mu D	WT
dI507	WT or	NS <sup>6</sup>	Mu D <sup>11</sup>
dF508	WT or	Mu D	NS <sup>12</sup>
V520F	WT	Mu D	WT
1717-1G>A	WT	Mu D	WT
G542X	WT	Mu D	WT
S549N	Mu D <sup>2</sup>	WT	WT
S549R(T>G)	HET	WT or	No Call <sup>7</sup>
G551D	WT	Mu D	WT
R553X	WT	WT	HET
A559T	WT	WT or	No Call <sup>8</sup>
R560T	WT	Mu D	WT
1898+1G>A	WT	Mu D	WT
1898+5G>T	WT	WT	WT
2183AA>G	WT	NS <sup>9</sup>	HET
2184delA	WT	Mu D	Wt D
2307insA	WT	WT	WT
2789+5G>A	WT	Mu D	WT
3120+1G>A	WT	Mu D	WT
Y1092X-C>G	WT	WT	WT
Y1092X-C>A	WT	WT	WT
M1101K	WT	WT	WT
R1162X	WT	Mu D	WT
3659delC	WT	Mu D	WT
S1255X(ex.19)	WT	WT	WT
S1255X(ex.20)	WT	WT	WT
3849+10kbC>T	WT	Mu D	WT
3876delA	WT	Mu D	WT
3905insT	WT	Mu D	WT
W1282X	WT	Mu D	WT
N1303K	WT	Mu D	WT
5T			
7T	CH <sup>3</sup>	CH <sup>10</sup>	5T / 7T D
9T			
I506V			
I507V	CH <sup>4</sup>	ND	I506V D
F508C			

- A No Call for both dI507 and dF508 in Bottle a may occur due to the presence of I507V and F508C, which prevents binding of dI507 and dF508 wild type (WT) probes. Actual genotype is WT for both dI507 and dF508.
- Genotype call for S549N in Bottle a is Mu D due to the presence of S549R(T>G), which prevents binding of S549N WT probe. Actual genotype is S549N/S549R.
- The unmasked genotype call for 5/7/9T in Bottle a is 7T D.
- The unmasked genotype call for I506V, I507V, F508C in Bottle a is I507V, F508C D.
- NS for R347H in Bottle b is expected due to the presence of R347P, which prevents binding of the R347H WT probe.
- NS for dI507 in Bottle b is expected due to the presence of dF508, which prevents binding of the dI507 WT probe.
- A No Call for S549R(T>G) in Bottle b may occur due to the presence of the G551D mutant, which prevents binding of the S549R(T>G) WT probe. Actual genotype is WT and may be seen in some labs.
- A No Call for A559T is expected due to the presence of the R560T mutant, which prevents binding of A559T WT probe. Actual genotype is WT and may be seen in some labs.
- NS for 2183AA>G in Bottle b is expected due to the presence of 2184delA, which prevents binding of the 2183AA>G WT probe.
- The unmasked genotype call for 5/7/9T in Bottle b is 9T D
- Genotype call for dI507 in Bottle c is Mu D due to the presence of I506V, which prevents binding of the dI507 WT probe on the wild type allele. Actual genotype is HET (dI507/ WT).
- NS for dF508 in Bottle c is expected call due to the presence of I506V and dI507, which prevents binding of the dF508 WT probe on the wild type allele.