

Puritan Batch 4 and 5 Report

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Prepared by:

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1. Swab Preparation

For simplicity, the swabs were coded as “C” and “D”.

Type: 25-825 1WCS TT FABUSA, Lot# 2675 Exp: 9/2015
50 swabs from beginning, middle and end of batch production (150 total)

25-805 1PC TT FABUSA, Lot# 2776 Exp: 11/2016
50 swabs from beginning, middle and end of batch production (150 total)

The swabs were used for analysis, as described below:

35 swabs: DNA test
32 test swabs (C1 – C32; D1 – D32)
3 positive control swabs
(C33/D33 beginning, C34/D34 middle, C35/D35 end)

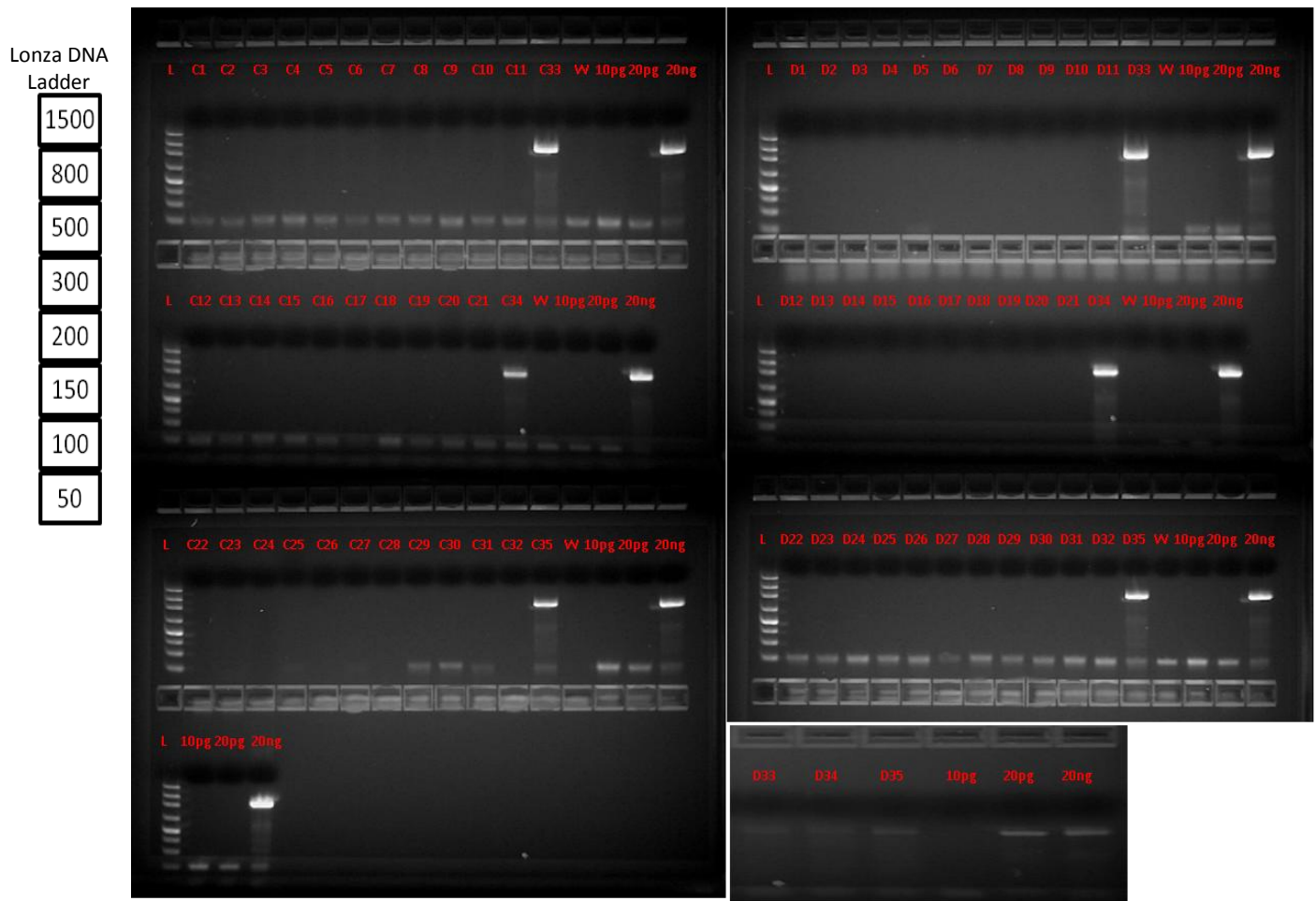
2. Test for DNA contamination

DNA was extracted from each swab using the QIAmp DNA Mini extraction kit and protocol for buccal swabs – the elution volume was 150 ul. For the three positive control swabs, a buccal sample was collected, allowed to dry overnight and then used for DNA extraction. To avoid contamination, DNA was extracted from the positive control swabs separately from the test swabs. Additional positive amplification controls (pac) of 10pg, 20pg and 20ng were added to the PCR.

5 ul from each sample was amplified for 40 cycles in a PCR reaction using primers specific for Alu. The total reaction volume was 20 ul. After PCR, 5 ul of each reaction was combined with 1 ul of 5x loading dye and run on a Lonza DNA flashgel. Images of the gels are shown below.

Figure 1.

DNA Test



FlashGel DNA 2.2% 16+1 DoubleTier Lot: 230163 Exp: 8-28-2011

Samples C1 – C11/D1 – D11 = Beginning, C12 – C21/D12 – D21 = Middle, C22 – C32/D22 – D32 = End, C33/D33 = Positive Extraction Control – Beginning, C34/D34 = Positive Extraction Control – Middle, C35/D35 = Positive Extraction Control – End. 10pg, 20pg, 20ng = Positive PCR Controls.

Result: No DNA was detected - within the limits of detection - on the test swabs, as evidenced by the lack of a band on the gels. The positive controls (C33 – C35; D33 – D35) were selected from each position within the batch (beginning, middle and end, respectively). These swabs performed as expected, revealing the presence of nucleic acid from a buccal swab preparation.

Lot 2675 (25-825 1WCS TT FABUSA) and Lot 2776 (25-805 1PC TT FABUSA) are DNA-free.