Report of Further Laboratory Investigations of Latex in Pandemic Vaccine Syringes Undertaken by Icosagen Laboratories

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Background

Natural rubber latex (NRL), which is derived from the rubber tree *Hevea brasiliensis*, contains particular proteins called allergens that can cause allergies in some people. Four NRL allergens have been identified as being clinically relevant to NRL allergy. These allergens are termed Hev b1, Hev b3, Hev b 5 and Hev b 6.02.

Icosagen's FITkit® test is based on a capture enzyme immunoassay method which is validated for extraction of the four latex allergens in phosphate buffered saline (PBS). The test uses highly purified and characterized allergens, and specific monoclonal antibodies, to quantify the four latex allergens in various products.

Icosagen tested 1mL syringes to determine whether latex leached out of the plunger tips of the syringes into PBS solution under a range of normal and 'worst case' contact conditions and extended holding times.

Method

Test 1 - Certificate No QA090128

PBS was withdrawn into 3 syringes and extracted immediately. The extracted solutions were combined (sample 1) for testing by the FITkit®assay.

Test 2 - Certificate No QA090129

PBS was withdrawn into 3 syringes in each of 6 sample groups. Each sample group was incubated for either 2 hours (samples 2 and 3), 4 hours (samples 4 and 5) or 6 hours (samples 6 and 7). The extracted solutions from 3 syringes in each sample group were combined for testing by the FITkit®assay.

Test 3 - Certificate No QA090130

Pieces of the latex plunger from the syringes were cut up and exposed to PBS for either 2 hours (samples 8 and 9), 4 hours (samples 10 and 11) or 6 hours (samples 12 and 13) prior to testing the PBS extract by the FITkit®assay.

Results

The four latex allergens (Hev b1, Hev b3, Hev b 5 and Hev b 6.02) were undetectable (UD) in the PBS extracts at the detection limits for each of the assays, as shown on the certificates of analysis for the three different test conditions:

- PBS withdrawn into syringes and immediately extracted. See test result shown on certificate No QA090128.
- PBS withdrawn into syringe and incubated for periods up to 6 hours prior to expulsion. See test result shown on certificate No QA090129.
- PBS incubated with cut-up pieces of the latex plunger for periods up to 6 hours. See test result shown on certificate No QA090130.

Conclusions

These results show that latex allergens could not be extracted from either the intact or disrupted latex plunger tips over a maximum contact period of 6 hours in phosphate buffered saline solutions at 4 degrees C. This demonstrates that there is an extremely low likelihood of latex allergens being present in the vaccine.