APPENDIX 1: HBV SEROLOGY TESTS QUALITY CONTROL

1. Murex HBsAg confirmatory test

Results of an assay were valid if the following criteria for the Controls were met:

Negative Control

- The mean A450 is less than 0.2.

HBsAg Positive Control

- The A450 of the Positive Control incubated with Control Reagent is more than 0.8 above the mean A450 of the Negative Control.
- The A450 of the Positive Control incubated with Specific Reagent is reduced by at least 80% of the Positive Control incubated with Control Reagent.

2. Murex anti-HBc (total) test

Results of an assay were valid if the following criteria for the Controls were met:

Negative Control minus Positive Control

- The mean A450 is between 0.5 and 2.2.

Positive Controls

- The mean A450 is less than 0.24.
3. Murex Anti-HBs test

Results of an assay were valid if the following criteria for the Calibrators were met:

Negative Control

- Mean Negative Control A450 must be less than 0.25.

Calibrators

- Mean 10 mlU/ml Calibrator A450 minus mean Negative Control A450 must be greater than 0.07.
- Mean 100 mlU/ml Calibrator A450 minus mean Negative Control A450 must be greater than or equal to 0.65.

4. DiaSorin HBeAg test (ETI – EBK PLUS)

Results of an assay were valid if the following criteria for the Calibrators and Controls were met:

Blank well

- The A450 value for the blank well must range between 0.000 and 0.150.

Calibrators

- The mean A450 for the calibrator must be greater than –0.020 and less than 0.120.
- Each calibrator A450 value must be greater than –0.020 and less than 0.120.

If any one of the calibrator A450 values did not meet these criteria, it was discarded and the mean value recalculated using the remaining two values. If more than one calibrator
absorbance value failed to meet these criteria, the run would be invalid and must be repeated.

**Negative and Positive Controls**

- The A450 for the negative control must be greater than –0.020 and less than 0.120.
- The A450 for the positive control must be greater than 0.500 and less than 2.500.
- The difference between the positive control absorbance value and the negative control absorbance value must be greater than 0.450.

**5. DiaSorin anti-HBe test (ETI – AB – EBK PLUS)**

Results of an assay were valid if the following criteria for the Calibrators and Controls were met:

**Blank well**

- The A450 value for the blank well must range between 0.000 and 0.150.

**Calibrators**

- The mean A450 for the calibrator must be greater than 0.500 and less than 2.500.
- Each calibrator A450 value must be greater than 0.500 and less than 2.500.

If any one of the calibrator absorbance values did not meet these criteria, it was discarded and the mean value recalculated using the remaining two values. If more than one calibrator absorbance value failed to meet these criteria, the run would be invalid and must be repeated.
Negative and Positive Controls

- The A450 for the negative control must be greater than 0.500 and less than 2.500.
- The A450 for the positive control must be greater than 0.050 and less than 0.300.
- The difference between the negative control absorbance value and the positive control absorbance value must be greater than 0.250.