

## REC Extraction Control

Suitable for Research and further Manufacturing Use as an IVD component

Catalog No:	MDX029
Lot No:	GR039-B085900
Storage Conditions:	-80°C
Component Lot No:	RC54-020206A
Expiry date:	December 2021

### Quality Control Parameters

Internal control designed to closely mimic test samples. Can be used to validate the extraction step and monitor any co-purification of PCR inhibitors

Analysis	Specification	Result
Functional	Quantitative PCR analysis comparing test and history RNA internal control. <u>Pass Criteria:</u> Test sample must amplify at a mean Ct of 27 - 30. The difference between test and history is less than 1 Ct. The negative control with and without reverse transcriptase is negative. The no template control with and without reverse transcriptase is negative. The no reverse transcriptase control is negative.	Passed

Authorised by Christopher Weatherall



## Control Mix 560

Suitable for Research and further Manufacturing Use as an IVD component

Catalog No:	MDX029
Lot No:	GR039-B085900
Shipping/Storage Conditions:	-20°C
Component Lot No:	CM560-020206A
Expiry date:	December 2021

### Quality Control Parameters

Internal control designed to closely mimic test samples. Can be used to validate the extraction step and monitor any co-purification of PCR inhibitors

Analysis	Specification	Result
Functional	Quantitative PCR analysis comparing test and history samples. <u>Pass Criteria:</u> Test sample must overlay the history sample with a difference between test and history of less than 1 Ct.	Passed
NTC Assay	Quantitative PCR analysis of test sample with a water control. <u>Pass Criteria:</u> Total positive samples must be less than 10% of the total NTC's run. Positive samples must have an average Ct value > 38.	Passed

Authorised by Christopher Weatherall



## MgCl<sub>2</sub> Solution, 50mM

Suitable for Research and further Manufacturing Use as an IVD component

Catalog No:	MDX029
Lot No:	GR039-B085900
Shipping / Storage Conditions:	-20°C
Component Lot No:	MG-2031.009
Expiry date:	December 2021

### Quality Control Parameters

Analysis	Specification	Result
Functional	Fragments of sizes 800bp and 3000bp are amplified with a dilution series of BIOTAQ™ DNA Polymerase, using standard conditions and 30 cycles. Single distinct bands were observed with agarose gel electrophoresis (ethidium stained).	Passed
DNA contamination	Quantitative PCR analysis with no template. Presence of <i>E. coli</i> and mouse genomic DNA checked. Test sample must amplify in line with a reference sample.	Passed
DNase contamination	Incubation of a 1Kb double stranded DNA fragment. Incubation for 4 hours at 37°C with dilution series of DNase I. Analysed by agarose gel electrophoresis. Test sample must show less degradation than the limit of detection $2.5 \times 10^{-3}$ U DNase.	Passed

Authorised by Christopher Weatherall

