APIS
Assay Technologies Ltd.

# APIS DPYD HT qPCR Kit

# Handbook

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# Handbook

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**APIS DPYD HT qPCR Kit is a product for Research Use Only.** Not to be used in diagnostic procedures.

All information contained in this manual was correct at the time of printing. Nevertheless, APIS continuously improves its product and reserves its rights to change specifications, devices, and maintenance procedures at any time and without notification.

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# 1. Intended Use

APIS DPYD HT qPCR Kit is intended to determine *DPYD* genotype from extracted genomic deoxyribonucleic acid (gDNA), or directly from human-derived EDTA whole blood samples and is to be used in basic, pharmaceutical, or chemical research. **The APIS DPYD HT qPCR Kit is not to be used in diagnostic procedures.**

APIS DPYD HT qPCR Kit is designed to detect the following *DPYD* alleles (Table 1).

*Table 1: Alleles detected by the APIS DPYD HT qPCR Kit.*

| Variant (NM_000110.4) | rsID |
|---|---|
| c.1905+1G>A | rs3918290 |
| c.1679T>G | rs55886062 |
| c.1129-5923C>G | rs75017182 |
| c.557A>G | rs115232898 |
| c.2846A>T | rs67376798 |
| c.868A>G | rs146356975 |
| c.2279C>T | rs112766203 |

# 2. Product Description

The APIS DPYD HT qPCR Kit enables the qualitative detection of specific *DPYD* gene variants using a high throughput, multiplexed real-time PCR format. The kit supports two sample types: extracted genomic DNA (gDNA) and EDTA whole blood. When using EDTA whole blood, the sample should be diluted to 1% (v/v) in nuclease-free water prior to testing. A total of 20µL of prepared sample is required to assess all variants detected by the kit.

The kit is delivered in a multiplex format, comprising four Primer Probe mixes (PP mixes). Each PP mix includes:

- Up to four allele-specific probes for variant and wildtype detection
- Up to two PCR primer pairs designed to amplify regions of interest with high specificity

These components have been carefully optimised to distinguish between wildtype and variant alleles with high analytical specificity. Each PP mix targets a defined set of *DPYD* alleles, and fluorophore labelling allows for clear differentiation of each allele type during real-time PCR analysis.

Details of the *DPYD* variants detected and the corresponding fluorophores used in each PP mix are provided in Table 2.

*Table 2: Variants/Alleles detected by each assay.*

| PP Mix | Variant (NM_000110.4) | Nucleic acid base detected | Alleles detected | Fluorophore |
|---|---|---|---|---|
| 1 | c.1905+1G>A | G | Wildtype | HEX ™ |
| | | A | Variant | FAM™ |
| | c.1679T>G | T | Wildtype | ATTO™550 |
| | | G | Variant | ROX™ |
| 2 | c.1129-5923C>G | C | Wildtype | HEX™ |
| | | G | Variant | FAM™ |
| 3 | c.557A>G | A | Wildtype | HEX™ |
| | | G | Variant | FAM™ |
| | c.2846A>T | A | Wildtype | ATTO™550 |
| | | T | Variant | ROX™ |
| 4 | c.868A>G | A | Wildtype | HEX™ |
| | | G | Variant | FAM™ |
| | c.2279C>T | C | Wildtype | ATTO™550 |
| | | T | Variant | ROX™ |

The probes are labelled with a 5′ reporter dye (FAM, HEX, ROX, or ATTO) and a downstream 3′ dye-free quencher. When a probe is intact the quencher results in suppression of the reporter fluorescence primarily by Förster-type energy transfer. The probes hybridise to the target sequence between the primers and during qPCR, the DNA polymerase enzyme cleaves the probe between the reporter and the quencher leading to an increase in detectable reporter fluorescence. This process occurs in every qPCR cycle. The increase in fluorescence is directly proportional to the target amplification during qPCR.

# 3. Material Provided

## 3.1 Kit Contents

**APIS DPYD HT qPCR Kit**
**(24 samples in singlicate + controls)**

| Component | Colour | Volume |
|---|---|---|
| Primer Probe Mix 1 | Red | 1x 250µL |
| Primer Probe Mix 2 | Orange | 1x 250µL |
| Primer Probe Mix 3 | Yellow | 1x 250µL |
| Primer Probe Mix 4 | Green | 1x 250µL |
| Enzyme Mix | White | 2x 1000µL |
| Positive Control (PC) | Black | 1x 210µL |
| No Template Control (NTC) | Clear | 1x 210µL |

# 4. Materials Required but Not Provided

## 4.1 Consumables

- Sterile pipette tips with filters
- Sterile microcentrifuge tubes
- PCR plates/seals or tubes compatible with a qPCR instrument

## 4.2 Equipment

- Real-Time PCR instrument (calibrated for FAM, HEX, ATTO550 and ROX fluorophores). Refer to the equipment user guide for further information on instrument calibration
- Calibrated adjustable volume pipettes
- Centrifuge (for microcentrifuge tubes)
- Plate centrifuge
- Vortex
- Adhesive Film Applicator

## 4.3 Reagents

- Nuclease free water for EDTA whole blood dilution

# 5. Reagent Storage and Handling

- If the kit is not frozen on arrival, the outer packaging is damaged or if any component of the kit is not present, please contact APIS Assay Technologies
- Store kit immediately on receipt at –25°C to –15°C in a constant-temperature freezer and protected from light
- Reagent stability studies are currently ongoing the initial kit stability claim will be included in a future version of this handbook
- Repeated thawing and freezing should be avoided
- To ensure optimal activity and performance, PP mixes must be protected from light to avoid photo bleaching
- Do not use expired or incorrectly stored components

# 6. Warnings and Precautions

This product is for **research use only**. Not intended for any diagnostic, clinical or medical purpose or objective.

# 7. General Precautions

- Avoid multiple freeze thaws of sample prior to testing with the APIS DPYD HT qPCR Kit
- All PP Mixes should be tested with each sample to minimise the possibility of obtaining false negative results
- Discard any samples or waste according to local safety procedures
- Reagents in the APIS DPYD HT qPCR Kit have been diluted optimally. Do not dilute reagents further.
- Controls provided should be tested with all reaction mixes on each qPCR run and are necessary to confirm correct APIS DPYD HT qPCR Kit performance and absence of contamination
- Take extreme care to prevent contamination of the kit components with the Positive Control reagent. Cap the tubes promptly after addition of each reagent.
- Take extreme care to prevent cross-contamination between samples. Cap the tubes promptly after addition of each sample and change tips between different samples
- Care should be taken to maintain sample traceability; sample tubes should be clearly labelled, and care should be taken when inputting sample information into the run template
- Do not remove the plate seal after the run has finished

# 8. Safety Information

- When working with chemicals, always wear suitable personal protective equipment (lab coat, disposable gloves, and protective eyewear). For more information, please consult the appropriate safety data sheets (SDS).
- EDTA whole blood should be treated as potentially biohazardous and set-up of the qPCR with this sample type should be performed in a Class II Microbiological Safety cabinet
- Any biohazardous waste should be disposed of according to local safety procedures

# 9. Procedure

## 9.1 Sample Preparation

### 9.1.1 Whole Blood Preparation

Whole blood (EDTA) should be diluted to 1% (v/v) using nuclease free water prior to testing with the APIS DPYD HT qPCR Kit.

Before performing the dilution homogenise the whole blood sample by gently inverting the collection tube several times. To ensure accurate pipetting and to avoid pipetting small volumes, prepare a minimum of 200µL of diluted blood per sample e.g. 2µL whole blood in 198µL nuclease free water. Vortex the diluted sample and briefly spin to collect.

During aspiration and dispensing, use very slow plunger movements and hold the tips in the liquid for a few seconds at the end of both aspiration and dispensing. Dilution of blood samples should be performed immediately prior to plate set up. Diluted material should not be stored, if a sample requires to be re-run a new dilution of blood should be performed.

### 9.1.2 DNA Sample Preparation

DNA should be extracted from samples using an extraction kit suitable for the purification of gDNA. Ensure that the chosen extraction kit is used according to the manufacturer's instructions. The input range of the assay is between 0.150-150 ng total gDNA input per reaction. 20µL of gDNA at a concentration between 0.03 – 30ng/µL is sufficient to assess all variants detected by the kit. Quantification of gDNA samples can be performed by using an appropriate quantification method (e.g. Fluorometer or UV spectrometer).

## 9.2 Plate Set Up & Cycling

The master mix contains all the components required for qPCR, except the extracted gDNA and/or diluted whole blood. Controls provided with the kit should be included in every run (negative control and positive control). Up to 22 samples can be analysed simultaneously in one qPCR run.

Thaw all kit components and samples (if frozen). It is important to mix the solutions completely before use to avoid localised differences in concentration, briefly vortex and spin to collect.

Reagent preparation and PCR set up can be performed at room temperature.

### 9.2.1 Master Mix Preparation

Prepare enough volume of master mix for one technical replicate per sample, one PC, one NTC, and one additional replicate (n+1) per mix to allow sufficient overage volume for PCR setup.

For each of the PP Mixes, prepare master mixes in microcentrifuge tubes immediately before use as per Table 3, adjusting the volumes depending on the required number of reactions. Using a vortex/centrifuge, mix the master mixes for at least 5 seconds and centrifuge to collect the volume at the bottom of the tube.

*Table 3: Master mix manufacture for N=1 sample.*

| Master Mix ID | Volume of Enzyme Mix per reaction (µL) | Primer Probe Mix | Volume of Primer Probe Mix per reaction (µL) |
|---|---|---|---|
| **Mix 1** | 10 | **PP mix 1** | 5 |
| **Mix 2** | 10 | **PP mix 2** | 5 |
| **Mix 3** | 10 | **PP mix 3** | 5 |
| **Mix 4** | 10 | **PP mix 4** | 5 |

### 9.2.2 Reaction Set Up

- Samples should be mixed for 5 seconds and then centrifuged briefly to collect
- Pipette 15µL of the corresponding Master Mix into each well changing tips between each mix
- Pipette 5µL of Sample/Positive Control or Negative Control into each well changing a tip between each addition
- An example of set-up in a 96-well PCR plate is shown in Figure 1
- To reduce a risk of cross contamination, negative and positive controls should always be positioned on the right side of the plate
- The final concentration of components per reaction is detailed in Table 4

*Table 4: Final concentration of components per reaction.*

| Component | Volume/reaction (µL) | Final concentration |
|---|---|---|
| **Enzyme Mix** | 10.0 | 1x |
| **Primer Probe Mix** | 5.0 | 1x |
| **Master Mix Total** | 15.0 | - |
| **Sample (1% diluted Blood/gDNA/PC/NTC)** | 5.0 | Variable |
| **Total Reaction Volume** | 20.0 | - |

- Seal the plate using a PCR plate seal and sealing tool
- Mix the plate/tubes by vortexing for 1 minute
- Centrifuge the plate/tubes for >1 minute to spin contents to bottom of the plate/tubes
- Visually assess for bubbles, if any are present, flick the plate/tubes and centrifuge for additional 30 seconds. Repeat until no bubbles are present.
- Place the plate/tubes into the compatible real time PCR instrument following the manufacturer's instructions


*Figure 1: Suggested Mix and Sample Layouts.*

## 9.3 Run Method

**Note:** Prior to set up ensure the instrument is calibrated for the dyes required for this experiment.

Refer to the selected real-time PCR platform user manual to set up the PCR run. The recommended qPCR cycling parameters are outlined in Table 5.

**Note:** A passive reference dye is not included in the kit – passive reference dye normalisation **should not** be selected.

*Table 5: Recommended cycling parameters for the APIS DPYD HT qPCR Kit.*

| Step | Step Number | Step Name | Temp | Time | Ramp Rate | Cycles |
|---|---|---|---|---|---|---|
| **Hold Stage** | 1 | Initial Activation | 95°C | 10 min | 1.6°C/s | 1 |
| **PCR Stage** | 1 | Denaturation | 94°C | 10 s | 1.6°C/s | 40 |
| | 2 | Annealing<br>Extension<br>Data Acquisition | 60°C | 30 s | 1.6°C/s | |

## 9.4 Threshold Setting

Targets, reporter dyes and quenchers for each PP Mix are shown in Table 6. Automatic baseline and threshold settings should be used. Users are recommended to empirically determine the suitability of thresholds for the qPCR instrument under use. The threshold should be set at the level of detection, or the point at which a reaction reaches a fluorescent intensity above background levels. For use with the Applied Biosystems™ QuantStudio™ 5 Dx (QS5 Dx) instrument we recommend thresholds provided in Table 6.

For further information of threshold setting on different qPCR platforms refer to Section 0: Appendix A: Threshold Setting.

*Table 6: Dye, Quencher and Threshold information for targets included in the APIS DPYD HT qPCR Kit.*

| PP Mix | Variant (NM_000110.4) | Nucleic acid base detected | Alleles detected | Fluorophore | Quencher* | ΔRn Threshold** |
|---|---|---|---|---|---|---|
| 1 | c.1905+1G>A | G | Wildtype | HEX | EDQ-MGB | 15,000 |
| | | A | Variant | FAM | EDQ-MGB | 35,000 |
| | c.1679T>G | T | Wildtype | ATTO550 | EDQ-MGB | 10,000 |
| | | G | Variant | ROX | EDQ-MGB | 15,000 |
| 2 | c.1129-5923C>G | C | Wildtype | HEX | Iowa Black FQ | 15,000 |
| | | G | Variant | FAM | Iowa Black FQ | 35,000 |
| 3 | c.557A>G | A | Wildtype | HEX | EDQ-MGB | 15,000 |
| | | G | Variant | FAM | EDQ-MGB | 40,000 |
| | c.2846A>T | A | Wildtype | ATTO550 | EDQ-MGB | 20,000 |
| | | T | Variant | ROX | EDQ-MGB | 20,000 |
| 4 | c.868A>G | A | Wildtype | HEX | EDQ-MGB | 15,000 |
| | | G | Variant | FAM | EDQ-MGB | 40,000 |
| | c.2279C>T | C | Wildtype | ATTO550 | EDQ-MGB | 15,000 |
| | | T | Variant | ROX | EDQ-MGB | 15,000 |

* Quencher is provided for information only; not required for run settings
** Thresholds provided for use with QS5 instrument

## 9.5 Run Export

Once the run is completed export the Ct (depending on instrument these may also be referred to as Cq or Cp) values. Refer to the selected real-time PCR platform user manual for analysis and export instructions.

Analysis can be completed either manually, as outlined below, or with the provided analysis spreadsheet. The spreadsheet includes recommended run and sample settings and is best suited for data from the QS5 Dx instrument.

### 9.5.1 Recommended Run Validity Criteria

**Note**: Ensure Ct values come from true amplification (sigmoidal amplification curves) rather than artifacts (linear or irregular curves) by examining the normalised fluorescence plot. Adjust the threshold and baseline settings as necessary, following the instructions in the qPCR instrument manual. Treat any data from artifacts as no amplification (see section 9.6).

**Note**: If using the QS5 Dx instrument the Amp status can be used to determine true amplification.

The run is deemed valid when the results for the negative control for all targets produce no amplification and each target amplifies within the positive control. The run validity criteria for use with the QS5 Dx instrument are outlined in Table 7. PC validity criteria should be verified if using an alternate instrument.

*Table 7: Recommended Run Validity Criteria for the APIS DPYD HT qPCR Kit.*

| Reaction Mix | Variant (NM_000110.4) | Nucleic acid base detected | Alleles detected | Fluorophore | Run Validity Criteria | |
|---|---|---|---|---|---|---|
| | | | | | Acceptable Positive Control (PC) Ct range | Negative Control (NTC) |
| **Mix 1** | c.1905+1G>A | G | Wildtype | HEX | ≥ 26.23 - ≤ 32.23 | Undetermined |
| | | A | Variant | FAM | ≥ 26.21 - ≤ 32.21 | |
| | c.1679T>G | T | Wildtype | ATTO550 | ≥ 24.74 - ≤ 30.74 | |
| | | G | Variant | ROX | ≥ 25.98 - ≤ 31.98 | |
| **Mix 2** | c.1129-5923C>G | C | Wildtype | HEX | ≥ 24.96 - ≤ 30.96 | |
| | | G | Variant | FAM | ≥ 25.46 - ≤ 31.46 | |
| **Mix 3** | c.557A>G | A | Wildtype | HEX | ≥ 24.82 - ≤ 30.82 | |
| | | G | Variant | FAM | ≥ 24.95 - ≤ 30.95 | |
| | c.2846A>T | A | Wildtype | ATTO550 | ≥ 25.12 - ≤ 31.12 | |
| | | T | Variant | ROX | ≥ 27.28 - ≤ 33.28 | |
| **Mix 4** | c.868A>G | A | Wildtype | HEX | ≥ 24.18 - ≤ 30.18 | |
| | | G | Variant | FAM | ≥ 25.71 - ≤ 31.71 | |
| | c.2279C>T | C | Wildtype | ATTO550 | ≥ 24.45 - ≤ 30.45 | |
| | | T | Variant | ROX | ≥ 25.30 - ≤ 31.30 | |

### 9.5.2 Sample Validity Criteria

Recommended sample validity criteria for QS5 Dx instrument are provided below. The suitability for the PCR instrument under use should be defined by the user.

It is recommended that for each sample the Ct value for the wildtype (ATTO550) target in PP Mix 1 (c.1679T) is **≤33.5**.

If a sample does not meet the acceptable Ct specification, the sample is invalid and should be repeated. Since the root cause of sample invalidity could be due to presence of inhibitor or sample input above or below the assay working range, it is recommended that when re-testing invalid samples the user tests dilutions of sample above and below the initial sample input. For example, if a diluted 1% (v/v) whole blood sample initially gives an invalid result with the kit, the user should repeat testing with 2% and 0.5% blood inputs to determine whether insufficient sample or presence of inhibitor is likely to be the root cause of the invalid result.

## 9.6 Results Interpretation

Ct values for the variant allele signal (FAM or ROX) relative to wildtype allele signal (HEX or ATTO550) for each variant should be used to support the research-based interpretation of sample genotype: homozygous wildtype, heterozygous (both alleles present) or homozygous variant.

To determine the genotype call for each variant, calculate the ΔCt using the equation below:

$$\Delta Ct = Ct\,(Wildtype) - Ct\,(Variant)$$

Important notes:

- Use Ct values from the same reaction mix and sample for both signals (wildtype and variant)
- If no amplification is detected for a target, assign a Ct value of 40
- If both wildtype and variant signals show no amplification for a given sample and variant, consider the results for that sample invalid

When using QS5 Dx instrument, ΔCt cut-off values presented in Table 8 may be used to guide genotype classification for research purposes only. Users of other instruments should determine the ΔCt cut-off for each variant empirically through testing known wildtype and heterozygous research samples for each variant.

*Table 8: Recommended cut-offs for establishing the genotype call*

| Variant (NM_000110.4) | ΔCt cut-off | | |
|---|---|---|---|
| | Wildtype Homozygous | Heterozygous | Variant Homozygous |
| c.1905+1G>A | < – 2.00 | ≥ – 2.00 ≤ 2.00 | > 2.00 |
| c.1679T>G | < – 3.00 | ≥ – 3.00 ≤ 1.00 | > 1.00 |
| c.1129-5923C>G | < – 3.00 | ≥ – 3.00 ≤ 1.00 | > 1.00 |
| c.557A>G | < – 2.00 | ≥ – 2.00 ≤ 2.00 | > 2.00 |
| c.2846A>T | < – 3.00 | ≥ – 3.00 ≤ 1.00 | > 1.00 |
| c.868A>G | < – 3.00 | ≥ – 3.00 ≤ 1.00 | > 1.00 |
| c.2279C>T | < – 3.00 | ≥ – 3.00 ≤ 1.00 | > 1.00 |

When analysing homozygous samples with the APIS DPYD HT qPCR Kit, low-level amplification of both variant and wildtype assays can be observed. Therefore, interpretation of genotype should be based on ΔCt values rather than amplification signals alone.

# 10. Kit Capabilities

## 10.1 Concordance

The concordance of the APIS DPYD HT qPCR Kit was demonstrated relative to gDNA from 29 cell line (Coriell Institute for Medical Research)[1] samples pre-characterised using research genotyping methods such as NGS, microarrays and qPCR, Seraseq DPYD DNA Mutation Mix (SeraCare, Cat. No. 0750-9502) and one synthetic DNA sample for each variant. Cell line DNA and Seraseq control was tested at 1.05ng/reaction) and the synthetic DNA was tested at 1000 copies/reaction.

100% agreement with the expected genotyping call was obtained for all samples tested (

Table 9).

Table 9: APIS DPYD HT qPCR Kit agreement with other research genotyping methods

| Variant (NM_000110.4) | N° Homozygous Wildtype samples tested | N° Heterozygous samples tested* | N° Homozygous Variant samples tested+ | N° of correctly genotyped samples |
|---|---|---|---|---|
| c.1905+1G>A | 24 | 5 | 2 | 31/31 |
| c.1679T>G | 27 | 3 | 1 | 31/31 |
| c.1129-5923C>G | 23 | 6 | 2 | 31/31 |
| c.557A>G | 24 | 6 | 1 | 31/31 |
| c.2846A>T | 24 | 6 | 1 | 31/31 |
| c.868A>G | 26 | 4 | 1 | 31/31 |
| c.2279C>T | 24 | 6 | 1 | 31/31 |

*One of which was the Seraseq DNA mutation mix, +One synthetic DNA per variant tested

Additionally, 100% agreement was obtained when comparing the result of 10 unique healthy donor EDTA whole blood sample results to matched extracted gDNA.

## 10.2 Troubleshooting

For information on troubleshooting, contact APIS Assay Technologies Technical Support via the website (https://www.apisassay.com/)

[1] The following DNA samples were obtained from the NIGMS Human Genetic Cell Repository at the Coriell Institute for Medical Research: NA06991, NA12004 and NA12248. The following DNA samples were obtained from the NHGRI Sample Repository for Human Genetic Research at the Coriell Institute for Medical Research: HG03196, HG03911, NA20797, NA20531, NA20515, NA19321, HG01914, NA20812, HG00185, HG02684, HG02645, HG03645, NA19921, NA19741, HG03771, HG02772, HG03716, NA20901, NA21114, NA21119, HG00118, HG00285, NA20362, HG00129, HG00332 & NA19207

# 11. Appendix A: Threshold Setting

The threshold should be set to a level higher than the baseline level of fluorescence but well below the plateau of the amplification plot. It must be positioned within the linear segment of the amplification curve, which indicates the detectable log-linear range of the PCR. For clarity, the threshold value should be established within the logarithmic view of the amplification plot to easily identify the log-linear phase of the PCR.

If multiple targets are used in the real-time experiment, the threshold needs to be determined individually for each target. Serial dilutions of template can be used to assess the correct threshold for your instrument, the threshold should be set across a range of template concentrations to determine the optimum threshold for each target (Figure 2).

Refer to the user guide of the qPCR platform in use for further information on threshold setting.

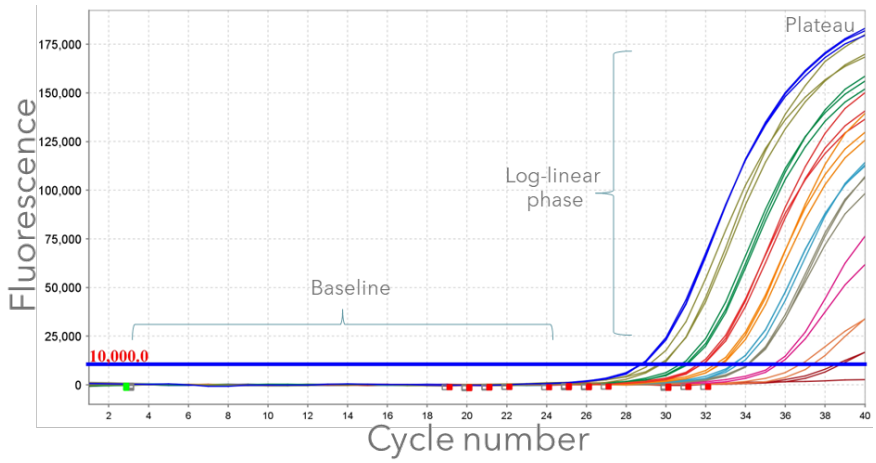


*Figure 2: Example of a linear amplification across a range of template concentrations (indicated by the coloured lines). The PCR threshold ( (blue line) was set close to the inflection point (or the point at which a reaction reaches a level of fluorescence above the background level of the reactions). The PCR threshold was set to ensure that all amplification curves generate a cycle number (Ct value)*

## 12. Symbols

| Symbol | Definition | Symbol | Definition |
|---|---|---|---|
|  | Batch code |  | Manufacturer |
|  | Catalogue number |  | Negative control |
|  | Caution |  | Positive control |
|  | Consult instructions for use or consult electronic instructions for use |  | Serial number |
|  | Contains sufficient for <24> tests |  | Temperature limit |
|  | Do not use if package is damaged and consult instructions for use |  | Date of Manufacture |
|  | Keep away from sunlight |  | Research Use Only |
|  | Distributor | | |

## 13. Contact Information

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## 14. Ordering Information

Visit the APIS website at https://www.apisassay.com/