

External Controls to Verify Rapid Test Accuracy

Simple and effective quality control: *Positivia* Rapid Test Controls provide confidence in rapid test reliability and enable compliance with regulatory requirements

CTK *Positivia* Rapid Test Controls are intended for use with CTK *OnSite* Rapid Tests as external assay controls to monitor test quality under circumstances such as:

Before testing:

- A new shipment arrives or a new lot is started
- The temperature during shipment or storage of the rapid test falls outside of the 2-30°C range
- The temperature of the test area falls outside of the 15-30°C range
- Training new technicians
- Product demonstrations of *OnSite* Rapid Tests

After testing:

- Confirming results that may conflict with other clinical findings
- Verifying a higher than expected frequency of positive or negative results
- Investigating the cause of repeated invalid results

OnSite Rapid Tests have internal controls built into each device to verify that the specimen volume is adequate and the solution flows as intended.

Positivia Rapid Test Controls provide users with external controls which serve as surrogate samples to evaluate the integrity of the test system and whether the person conducting the test performs it correctly. They may be purchased separately or included in each rapid test kit to create a conveniently portable yet comprehensive system.

Each *Positivia* Rapid Test Assay Control Kit contains:

1. **Lyophilized Positive Control:** Can be transported and stored together with rapid test kits at 2-30°C.
2. **Liquid Negative Control:** Packaged in a capped dropper bottle for easy dispensing or reconstitution of the positive control. Perfect for QC in the field!

Positivia Controls are produced using recombinant protein engineering technology in our ISO 13485:2003 certified facility to ensure precise performance and reliability. No biohazardous materials included.

Positivia Controls can potentially be used with other rapid test brands; results obtained from use with another rapid test can not be guaranteed unless validation of performance has been documented.



Positivia Rapid Test Control Kits

Catalog	Control Kit	Intended Rapid Test	Shelf Life	Storage
C0010	<i>Positivia</i> Malaria Ag Control Kit	<i>OnSite</i> Malaria Pf/Pv Ag Rapid Test (R0112C) <i>OnSite</i> Malaria Pf/Pan Ag Rapid Test (R0113C) <i>OnSite</i> Malaria Pf Ag Rapid Test (R0114C)	12 months	2-30°C
C0018	<i>Positivia</i> HIV-1 P24 Ag Control Kit	<i>OnSite</i> HIV Ag/Ab 4th Gen. Rapid Test (R0018C)	12 months	2-30°C
C0063	<i>Positivia</i> Dengue Ag Control Kit	<i>OnSite</i> Dengue Ag Rapid Test (R0063C)	6 months	2-30°C
C0192	<i>Positivia</i> H. pylori Ag Control Kit	<i>OnSite</i> H. pylori Ag Rapid Test (R0192C)	6 months	2-30°C
C2011	<i>Positivia</i> FOB Control Kit	<i>OnSite</i> FOB Rapid Test (R2011C)	6 months	2-30°C

Positvia Rapid Test Control Kits at a Glance

C0010 Malaria Ag Rapid Test Control Kit



Intended use	As an external assay control for the OnSite Malaria Ag Rapid Tests
Content	PF-HRP II Ag Positive Control PF-LDH Ag Positive Control Pv-LDH Ag Positive Control Malaria Negative Control
Physical status	Lyophilized powder
Shelf life	12 months
Storage	2-30°C

C0018 HIV-1 P24 Ag Rapid Test Control Kit



Intended use	As an external assay control for the OnSite HIV Ag/Ab 4th Gen Rapid Test
Content	HIV-1 P24 Ag Positive Control HIV-1 P24 Ag Negative Control
Physical status	Lyophilized powder
Shelf life	12 months
Storage	2-30°C

C0063 Dengue Ag Rapid Test Control Kit



Intended use	As an external assay control for the OnSite Dengue Ag Rapid Test
Content	Dengue Ag Positive Control Dengue Ag Negative Control
Physical status	Lyophilized powder
Shelf life	6 months
Storage	2-30°C

C0192 H. pylori Ag Rapid Test Control Kit



Intended use	As an external assay control for the OnSite H. pylori Ag Rapid Test
Content	H. pylori Ag Positive Control H. pylori Ag Negative Control
Physical status	Lyophilized powder
Shelf life	6 months
Storage	2-30°C

C2011 FOB Rapid Test Control Kit



Intended use	As an external assay control for the OnSite FOB Rapid Test
Content	FOB Positive Control FOB Negative Control
Physical status	Lyophilized powder
Shelf life	6 months
Storage	2-30°C

