POSITIVE CONTROL

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Positive Control Instructions for Use

FOR IN VITRO DIAGNOSTIC USE
EN
FOR PROFESSIONAL USE ONLY
Not for self-testing
Not for near patient testing
References: (see table, point III.3.)

I. INTRODUCTION

The rapid *in vitro* diagnostic tests that detect an antigen associated with an infectious disease by an antibody - antigen reaction allow to identify the presence of a pathogenic agent or a part of this agent in a sample in order to help in establishing the diagnostic of the disease or infection.
The availability of non-hazardous antigen positive controls is an essential and central component in the use of immunodiagnostic assays.
They can be used for verification of immunoassay instruments (devices), manufacturing quality management system, educational and R&D purposes.
Coris BioConcept has developed a range of positive viral, bacterial and parasitic control products. These references are in liquid or freeze-dried form and contain a non-hazardous antigen preparation for use with an immunoassay.
The current correspondence of positive controls and IVD test kits is listed in the table below (point III.3).

II. PRINCIPLE OF THE TEST

Each positive control must be prepared with the specific dilution buffer of the targeted immunoassay kit. Once diluted, the C+ is brought into contact with the strip or the cassette device, the solution migrates by passive diffusion and the control reagent binds first to a conjugated antibody then to the antibody coated on the test line, thereby causing a colored line to appear on the specific test line and allows to validate the assay. The solution continues to migrate to reach a second reagent that binds the migration control conjugate, thereby producing a red control line that confirms that the immunochromatographic migration has worked properly.

III. REAGENTS AND MATERIALS

1. Positive control (1)

One plastic or glass vial containing a powder or a liquid (0.7-1-mL) positive control antigen. Each vial contains reagent for a minimum of 4 tests.

2. Instruction for use (1)

3. Correspondence table of positive controls and IVD test kits:

Reagents' quality is guaranteed with the kits listed in the table. Use with other immunoassays has not yet been established.

Reference	Product name	Antigen	To use with Coris BioConcept's kits	Packaging
P-1001	Rotavirus Positive Control	Rotavirus	Rota-Strip (C-1001) Combi-Strip (C-1004) Combi K-SeT (K-1204, K-1504) GastroVir K-SeT (K-1516)	Freeze-dried
P-1002	Adenovirus Positive Control	Adenovirus type 40	Combi-Strip (C-1004) Combi K-Set (K-1204, K-1504) Adeno Respi-Strip (C-1009) Adeno Respi K-Set (K-1209, K-1509) GastroVir K-Set (K-1516)	Freeze-dried
P-1006	RSV Positive Control	RSV	RSV Respi-Strip (C-1006) RSV K-SeT (K-1206, K-1506)	Freeze-dried
P-1010	Influenza A Positive Control	Nucleoprotein	Influ A+B K-SeT (K-1212, K-1512)	Liquid
P-1013	Giardia Positive Control	*Giardia* specific antigen	Giardia-Strip (C-1013) Giardia K-SeT (K-1513) Crypto/Giardia Duo-Strip (C-1018)	Liquid
P-1019	Pylori Positive Control	*H. pylori* specific antigen	Pylori-Strip (C-1019) Pylori K-SeT (K-1519)	Liquid
P-1015	Legionella Positive Control	*L. pneumophila* extract	Legionella K-SeT (K-1215, K-1515)	Liquid
P-1020	C difficile Positive Control	GDH from *C. difficile*	Clostridium K-SeT (K-1220, K-1520)	Freeze-dried
P-10R11	RESIST penta O.K.N.V.I control (5 vials of individual controls)	OXA-48 KPC NDM VIM IMP	OXA-48 K-SeT (K-15R1) IMP K-SeT (K-15R10) RESIST-3 O.O.K. K-SeT (K-15R4) RESIST-3 O.K.N. K-SeT (K-15R5) O.K.N.V.I. RESIST-5 (K-15R11)	Freeze-dried
P-10R4-1	OXA-163 Positive Control	OXA-163	RESIST-3 O.O.K. K-SeT (K-15R4)	Freeze-dried
P-10R7	OXA-23 Positive Control	OXA-23	OXA-23 K-SeT (K-15R7)	Freeze-dried
P-1023	COVID-19 Ag Positive Control	Nucleoprotein	COVID-19 Ag Respi-Strip (C-1023, C-1123, C-1223) COVID-19 Ag K-SeT (K-1525)	Freeze-dried

IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with good laboratory practices.
- All reagents are for *in vitro* diagnostic use only
- To be used in conjunction with the IVD test kits listed in the table (point III.3).
- Vial must be opened with care
- Do not use any damaged kit contents.
- Wear gloves when handling positive controls
- Reagents quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in this Information For Use package insert.

V. WASTE DISPOSAL

- Dispose of gloves, test tubes and used devices in accordance with good laboratory practices.
- Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

VI. STORAGE

- Each Positive Control may be kept at the temperature indicated on the vial and used until the shelf-life date indicated on the packaging.
-For Positive Control coming in freeze-dried form: once rehydrated, should be stored no more than 2 weeks at 4°C.
- No freezing advised.

VII. HANDLING AND COLLECTION

No special handling required for these products.

VIII. PROCEDURE

PROTOCOL FOR USE OF FREEZE-DRIED CONTROLS:

1. To be rehydrated with 1 mL of distilled water.
2. Transfer 200 µL of positive control in a tube.
3. Add 6 drops of the dilution buffer (provided in the diagnostic kit) to reach a dilution ratio of 1/2.
4. Stir thoroughly to homogenize the solution.
5. Use the mixture accordingly to IVD test kit instructions

PROTOCOL FOR USE OF LIQUID CONTROLS:

1. Transfer 200 µL of positive control in a tube.
2. Add 6 drops of the dilution buffer (provided in the diagnostic kit) to reach a dilution ratio of 1/2.
3. Stir thoroughly to homogenize the solution.
4. Use the mixture accordingly to IVD test kit instructions.

IX. EXPECTED RESULTS

With the IVD test kits listed in the table (point III.3), **Positive test result**, i.e. a visible reddish-purple band appears at the Test line in addition to a reddish-purple band at the Control line (C). Intensity of the test line may vary according to the batch of kit used. Any reddish-purple Test line, even weak, should be considered as a positive result.
Invalid test result: The absence of a specific signal on both lines indicates a failure in the procedure. Repeat invalid tests with a new IVD test.

X. QUALITY CONTROL

In accordance with good laboratory practices, we recommend checking the IVD test performance regularly according to the laboratory requirements by using an appropriated positive control. Note that a Negative Control is also available for purchase. This is the CTR-1000 containing an *S. pyogenes* extract. With Negative Control (Ref CTR-1000), no signal should appear at the test line in all the kits of our panel.

XI. REPEATABILITY AND REPRODUCIBILITY

To check intra-batch accuracy (repeatability), the same positive control and a buffer solution were processed 15 times on an IVD test kit of the same production batch in the same experimental conditions. All observed results were confirmed as expected.
To check inter-batch accuracy (reproducibility), some positive controls were processed on an IVD test kit from three different production batches. All results were confirmed as expected.

XII. LIMITS OF THE KIT

The positive control kit is qualitative, it is not a calibrator that predicts a quantitative value of the IVD test used

XIII. TECHNICAL PROBLEMS / COMPLAINTS

If you face a technical problem or if performances do not correspond with those indicated in this package insert:

1. Write the lot number of the kit concerned
2. If possible, keep the sample in the appropriate storage condition during the complaint management
3. Contact Coris BioConcept (client.care@corisbio.com) or your local distributor

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REF	Catalogue number		Manufacturer
IVD	*In vitro* diagnostic medical device		Temperature limits
Σ	Contains sufficient for <n> tests	LOT	Lot number
	Consult instructions for use		Do not reuse
	Keep dry		Use by
	Not for self-testing		Not for near patient testing