

# EQA Schemes in Virus Diagnostics March 2016



EQA schemes closed

**Information on sample properties**



# INSTAND e.V.

*in cooperation with:*

Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV)  
Gesellschaft für Virologie e.V. (GfV)  
Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V. (DGHM)

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# INSTAND External Quality Assessment Schemes – March 2016

## Virus Immunology Virus Genome Detection by PCR/NAT

### Information on sample properties

Dear colleagues,

You have participated in one or several of the INSTAND external quality assessment (EQA) schemes in virus diagnostics of March 2016.

The INSTAND EQA schemes – March 2016 for virus immunology and virus genome detection by PCR/NAT are now closed.

For orientation, you receive information on the properties of the samples which were tested in the respective EQA scheme of March 2016.

The pre-evaluation of these EQA schemes which you usually receive, will be supplied in due time together with participation documents (certificate of successful participation, statement of participation, statement of individual results).

**Please note that information on  
- target values/target value intervals for quantitative results and  
- final evaluation of the respective samples  
will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding EQA program.**

For questions, please do not hesitate to contact us.

Thank you very much for your kind cooperation

Prof. Dr. H. Zeichhardt

Priv.-Doz. Dr. O. Donoso Mantke

**Table 1: EQA Schemes Virus Immunology - March 2016**  
**Information on sample properties**

| Program                               | Group | RiliBÄK        | Analyte         | Sample | Sample properties |          |  |
|---------------------------------------|-------|----------------|-----------------|--------|-------------------|----------|--|
|                                       |       |                |                 |        | qualitative       | dilution | sample source  |
| Cytomegalovirus (Ab) serum            | 351   | conform to B 2 | anti-CMV-IgG    | 351047 | positive          |          | past CMV infection (two healthy blood donors)  |
|                                       |       |                | anti-CMV-IgM    |        | avidity: high     |          |  |
|                                       |       |                | anti-CMV-IgG    | 351048 | positive          |          | past CMV infection (two healthy blood donors)  |
|                                       |       |                | anti-CMV-IgM    |        | avidity: high     |          |  |
| Dengue-viruses* (Ab and NS1-Ag) serum | 350*  | conform to B 2 | anti-Dengue-IgG | 350046 | positive          | 1 : 2    | Patient D12 with an <b>acute</b> primary dengue virus infection (DENV-1), negative for dengue virus RNA; traveller returned from South Thailand, blood collected <b>8 days after onset of disease</b>  |
|                                       |       |                | anti-Dengue-IgM |        | positive          |          |  |
|                                       |       |                | Dengue NS1-Ag   |        | positive          |          |  |
|                                       |       |                | anti-Dengue-IgG | 350047 | negative          | 1 : 14   | Dengue virus serum D21, representing an <b>acute</b> primary dengue virus infection <b>positive for NS1-Ag only</b> : serum of a healthy blood donor without signs of an acute or past dengue virus infection spiked with a cell culture propagated virus (DENV-2; heat inactivated) |
|                                       |       |                | anti-Dengue-IgM |        | negative          |          |  |
|                                       |       |                | Dengue NS1-Ag   |        | positive          |          |  |
|                                       |       |                | anti-Dengue-IgG | 350048 | positive          | 1 : 1.08 | Pool of sera from one and the same patient D22 with a <b>past</b> primary dengue virus infection (DENV-2), traveller returned from Zanzibar, blood collected <b>4 - 18 months after onset of disease</b> ;   |
|                                       |       |                | anti-Dengue-IgM |        | negative          |          |  |
|                                       |       |                | Dengue NS1-Ag   |        | negative          |          |  |
|                                       |       |                | anti-Dengue-IgG | 350049 | positive          | 1 : 1.56 | Pool of sera from one and the same patient D23 with a <b>recent</b> primary dengue virus infection (DENV-2), traveller returned from Thailand, blood collected <b>3 - 4 weeks after onset of disease</b>   |
|                                       |       |                | anti-Dengue-IgM |        | positive          |          |  |
|                                       |       |                | Dengue NS1-Ag   |        | negative          |          |  |

Non-marked samples derive from independent preparations.

\* The EQA program Dengue viruses (350) is performed in cooperation with Bernhard-Nocht-Institut, Hamburg (Nationales Referenzzentrum für tropische Infektionserreger und WHO Collaborating Centre for Arbovirus and Haemorrhagic Fever Reference and Research; Prof. Dr. Stephan Günther, Prof. Dr. Dr. Jonas Schmidt-Chanasit and Dr. Petra Emmerich).

**Please note that information on**  
**- target values/target value intervals for quantitative results and**  
**- final evaluation of the respective samples**  
**will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding EQA program.**

**Table 1 (contd.): EQA Schemes Virus Immunology - March 2016**  
**Information on sample properties**

| Program                                 | Group  | RiliBÄK                       | Analyte          | Sample  | Sample properties  |          |   |   |
|---|--------|-------------------------------|------------------|---|--|----------|---|---|
|   |        |                               |                  |   | qualitative  | dilution | sample source   |   |
| Hanta-<br>viruses*<br>(Ab)<br><br>serum | 355*   | <i>conform<br/>to<br/>B 2</i> | anti-Dobrava-IgG | 355045  | positive   | 1 : 3    | Patient H13 with a <b>past Dobrava-Belgrade virus infection, probably acquired in Brandenburg, Germany</b> , anamnesis concerning a stay abroad outside Europe excluded at onset of disease hospitalization necessary, characteristic symptoms such as elevated creatinine, flu-like symptoms and abnormal fatigue<br>blood collected <b>approx. 3 years and 7 month after onset of disease</b><br>diluted with sera from healthy blood donors (pool) |   |
|   |        |                               | anti-Dobrava-IgM |   | negative   |          |   |   |
|   |        |                               | anti-Dobrava-IgG | 355046  | positive   | 1 : 2    |   | Patient H20 with an <b>acute Dobrava-Belgrade virus infection, acquired in Brandenburg, Germany</b> , anamnesis concerning a stay abroad outside Europe excluded at onset of disease hospitalization necessary; characteristic flu-like symptoms with fever and in addition acute renal failure<br>blood collected <b>approx. 3 weeks after onset of disease (serum is negative for Hantavirus RNA)</b><br>diluted with sera from healthy blood donors (pool) |
|   |        |                               | anti-Dobrava-IgM |   | positive   |          |   |   |
| anti-Puumala-IgG                        | 355047 | positive                      | 1 : 2            | Patient H11 with a <b>past Puumala virus infection acquired in North Rhine Westphalia, Germany</b> , anamnesis concerning a stay abroad outside Europe excluded at onset of disease hospitalization necessary, characteristic flu-like symptoms with fever<br>blood collected <b>approx. 4 weeks after onset of disease</b><br>diluted with sera from healthy blood donors (pool) |  |          |   |   |
| anti-Puumala-IgM                        |        | negative                      |                  |   |  |          |   |   |
| anti-Hanta-IgG                          | 355048 | negative                      |                  |   | Serum of healthy blood donors (pool) without signs of an acute or past hanta virus infection |          |   |   |
| anti-Hanta-IgM                          |        | negative                      |                  |   |  |          |   |   |

Non-marked samples derive from independent preparations.

\* The EQA program Hantaviruses (355) is performed in cooperation with Nationalen Konsiliarlaboratorium für Hantaviren (Charité - Universitätsmedizin Berlin, Campus Mitte, Institut für Medizinische Virologie, Labor Berlin-Charité Vivantes GmbH, Prof. Dr. D. H. Krüger, Prof. Dr. J. Hofmann).

**Please note that information on**  
**- target values/target value intervals for quantitative results and**  
**- final evaluation of the respective samples**  
**will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding EQA program.**

**Table 1 (contd.): EQA Schemes Virus Immunology - March 2016  
Information on sample properties**

| Program   | Group    | RiliBÄK   | Analyte      | Sample         | Sample properties                                  |               |   |                                       |                                      |
|---|----------|---|--------------|----------------|--|---------------|---|---------------------------------------|--------------------------------------|
|   |          |   |              |                | qualitative  | dilution      | sample source                             |                                       |                                      |
| Hepatitis A virus (Ab) serum                                | 343      | mandatory: B 2  | anti-HAV     | 343093         | positive<br><i>target values will be specified</i> | (a) 1 : 200   | anti-HAV-IgG positive healthy blood donor |                                       |                                      |
|   |          |   | anti-HAV     | 343094         | positive<br><i>target values will be specified</i> | (a) 1 : 100   |   |                                       |                                      |
|   |          |   | anti-HAV-IgM | 343095         | positive   | 1 : 20        | acute hepatitis A infection               |                                       |                                      |
|   |          |   | anti-HAV-IgM | 343096         | positive   | 1 : 25        | acute hepatitis A infection               |                                       |                                      |
| Hepatitis B virus (prog. 1) (HBsAg anti-HBs anti-HBc) serum | 344      | mandatory: B 3  | HBsAg        | 344277         | negative<br><i>target values will be specified</i> |               | negative healthy blood donors (pool)      |                                       |                                      |
|   |          |   | HBsAg        | 344278         | positive<br><i>target values will be specified</i> | (b) 1 : 3 000 | chronic hepatitis B                       |                                       |                                      |
|   |          |   | HBsAg        | 344279         | positive<br><i>target values will be specified</i> | (b) 1 : 1 000 |   |                                       |                                      |
|   |          |   | HBsAg        | 344280         | positive<br><i>target values will be specified</i> | (b) 1 : 9 000 |   |                                       |                                      |
|   |          | mandatory: B 2  | anti-HBs     | 344281         | positive<br><i>target values will be specified</i> | (c) 1 : 1 250 |   | anti-HBs positive healthy blood donor |                                      |
|   |          |   | anti-HBs     | 344282         | negative<br><i>target values will be specified</i> |               | negative healthy blood donors (pool)      |                                       |                                      |
|   |          |   | anti-HBs     | 344283         | positive<br><i>target values will be specified</i> | (c) 1 : 2 500 | anti-HBs positive healthy blood donor     |                                       |                                      |
|   |          |   | anti-HBs     | 344284         | positive<br><i>target values will be specified</i> | (c) 1 : 5 000 |   |                                       |                                      |
|   |          | mandatory: B 2  | anti-HBc     | 344285         | positive   | (d) 1 : 300   | chronic hepatitis B (negative for HBeAg)  |                                       |                                      |
|   |          |   | anti-HBc     | 344286         | positive   | (d) 1 : 600   |   |                                       |                                      |
|   |          |   | anti-HBc     | 344287         | positive   | (d) 1 : 150   |   |                                       |                                      |
|   |          |   | anti-HBc     | 344288         | negative   |               | negative healthy blood donors (pool)      |                                       |                                      |
|   |          | Hepatitis B virus (prog. 2) (anti-HBc-IgM HBeAg anti-HBe) serum | 345          | mandatory: B 2 | anti-HBc-IgM                                       | 345139        | positive                                  | 1 : 55                                | acute hepatitis B infection          |
|   |          |   |              |                | anti-HBc-IgM                                       | 345140        | negative                                  |                                       | negative healthy blood donors (pool) |
|   |          |   |              | mandatory: B 3 | HBeAg  | 345141        | positive                                  | (e) 1 : 350                           | chronic hepatitis B                  |
|   |          |   |              |                | HBeAg  | 345142        | positive                                  | (e) 1 : 700                           |                                      |
| mandatory: B 2  | anti-HBe |   |              | 345143         | positive   | (f) 1 : 80    | chronic hepatitis B (negative for HBeAg)  |                                       |                                      |
|   | anti-HBe |   |              | 345144         | positive   | (f) 1 : 40    |   |                                       |                                      |

a, b, c, d, e, f: Marked samples derive from corresponding stock materials diluted in consecutive steps.

Non-marked samples derive from independent preparations.

**Please note that information on  
- target values/target value intervals for quantitative results and  
- final evaluation of the respective samples  
will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding EQA program.**

**Table 1 (contd.): EQA Schemes Virus Immunology - March 2016  
Information on sample properties**

| Program  | Group | RiliBÄK  | Analyte                 | Sample   | Sample properties    |                |   |
|--|-------|--|-------------------------|----------|----------------------|----------------|---|
|  |       |  |                         |          | qualitative          | dilution       | sample source   |
| Hepatitis C virus<br>(Ab and HCV-Ag)<br><br>serum*<br><br>plasma** | 346   | <u>anti-HCV</u><br><b>mandatory:</b><br><b>B 2</b> | anti-HCV<br>HCV antigen | 346093*  | positive<br>negative | 1 : 7.1        | Condition after<br>chronic hepatitis C<br>(subtype 1b;<br>successful therapy)                 |
|  |       |  | anti-HCV<br>HCV antigen | 346094** | positive<br>positive | 1 : 50         | chronic hepatitis C<br>(subtype 1b)   |
|  |       | <u>HCV Ag</u><br><b>mandatory:</b><br><b>B 3</b>   | anti-HCV<br>HCV antigen | 346095*  | negative<br>negative |                | negative healthy blood<br>donors (pool)   |
|  |       |  | anti-HCV<br>HCV antigen | 346096** | positive<br>positive | 1 : 10         | chronic hepatitis C<br>(subtype 3a)   |
| HIV-1/<br>HIV-2<br>(Ab)<br><br>serum                               | 335   | <b>mandatory:</b><br><b>B 2</b>                    | anti-HIV-1              | 335093   | positive             | (g) 1 : 80     | HIV-1 infection   |
|  |       |  | anti-HIV-1/2            | 335094   | negative             |                | negative healthy blood<br>donors (pool)   |
|  |       |  | anti-HIV-1              | 335095   | positive             | (g) 1 : 320    | HIV-1 infection   |
|  |       |  | anti-HIV-1              | 335096   | positive             | (g) 1 : 160    |   |
| HIV-1<br>p24 Ag<br><br>serum                                       | 337   | <b>mandatory:</b><br><b>B 3</b>                    | p24 Ag                  | 337047   | positive             | (h) 1 : 76 000 | HIV-1 infection<br>(spiked serum pool of<br>negative blood donors;<br>HIV-1 heat inactivated) |
|  |       |  | p24 Ag                  | 337048   | positive             | (h) 1 : 19 000 |   |

g, h: Marked samples represent dilutions from the corresponding stock materials.

Non-marked samples derive from independent preparations.

**Please note that information on  
- target values/target value intervals for quantitative results and  
- final evaluation of the respective samples  
will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding  
EQA program.**

**Table 2: EQA Schemes Virus Genome Detection by PCR/NAT - March 2016  
Information on sample properties**

| Program  | Group | RiliBÄK                         | Sample | Sample properties                         |          |   |  |  |
|--|-------|---------------------------------|--------|---|----------|---|--|--|
|  |       |                                 |        | qualitative<br>(note on<br>geno-/subtype) | dilution | Target value of all methods<br>(provisional data) |  |  |
|  |       |                                 |        |   |          | copies/ml   | IU/ml                                      |  |
| BK virus<br>(DNA)<br>suspension<br>of urine          | 364   | <i>conform<br/>to<br/>B 3</i>   | 364017 | positive                                  | (a)      | 1 : 1 000   | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 364018 | positive                                  |          | 1 : 1 000   |  |  |
|  |       |                                 | 364019 | negative                                  |          | 1 : 100   |  |  |
|  |       |                                 | 364020 | positive                                  | (a)      | 1 : 100 000                                       |  |  |
| Chikungunya<br>virus<br>(RNA)<br>cell lysates        | 392   | <i>conform<br/>to<br/>B 3</i>   | 392009 | positive                                  | (b)      | 1 : 100<br>(inactivated)                          | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 392010 | positive                                  |          | 1 : 100<br>(inactivated)                          |  |  |
|  |       |                                 | 392011 | positive                                  | (b)      | 1 : 1 000<br>(inactivated)                        |  |  |
|  |       |                                 | 392012 | negative                                  |          | -----   |  |  |
| CMV<br>(DNA)<br>plasma                               | 365   | <b>manda-<br/>tory:<br/>B 3</b> | 365093 | positive                                  | (c)      | 1 : 1 000   | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 365094 | positive                                  | (c)      | 1 : 316   |  |  |
|  |       |                                 | 365095 | positive                                  | (c, d)   | 1 : 3 162   |  |  |
|  |       |                                 | 365096 | positive                                  | (c)      | 1 : 100   |  |  |
| CMV<br>(DNA)<br><b>training<br/>progr.</b><br>plasma | 368   | <i>conform<br/>to<br/>B 3</i>   | 368017 | positive                                  | (c)      | 1 : 10 000  | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 368018 | positive                                  | (c)      | 1 : 31 628  |  |  |
|  |       |                                 | 368019 | positive                                  | (c)      | 1 : 100 000                                       |  |  |
|  |       |                                 | 368020 | positive                                  | (c, d)   | 1 : 3 162   |  |  |
| HAV<br>(RNA)<br>spiked<br>plasma                     | 377   | <b>manda-<br/>tory:<br/>B 3</b> | 377093 | positive                                  | (e)      | 1 : 20 000  | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 377094 | positive                                  | (e)      | 1 : 5 000   |  |  |
|  |       |                                 | 377095 | positive                                  | (e)      | 1 : 1 250   |  |  |
|  |       |                                 | 377096 | positive                                  | (e)      | 1 : 10 000  |  |  |
| HBV<br>(DNA)<br>plasma                               | 361   | <b>manda-<br/>tory:<br/>B 3</b> | 361093 | positive                                  | (f, g)   | 1 : 50 000  | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 361094 | positive                                  | (f)      | 1 : 400   |  |  |
|  |       |                                 | 361095 | negative                                  |          | -----   |  |  |
|  |       |                                 | 361096 | positive                                  | (f)      | 1 : 2 000   |  |  |
| HBV<br>(DNA)<br><b>training<br/>progr.</b><br>plasma | 378   | <i>conform<br/>to<br/>B 3</i>   | 378017 | positive                                  | (f)      | 1 : 250 000                                       | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 378018 | positive                                  | (f, g)   | 1 : 50 000  |  |  |
|  |       |                                 | 378019 | positive                                  | (f)      | 1 : 1 250 000                                     |  |  |
|  |       |                                 | 378020 | positive                                  | (f)      | 1 : 6 250 000                                     |  |  |
| HCV<br>(RNA)<br>plasma                               | 362   | <b>manda-<br/>tory:<br/>B 3</b> | 362093 | positive<br>(subtype 3a)                  | (h)      | 1 : 135   | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 362094 | positive<br>(subtype 3a)                  | (h)      | 1 : 45  |  |  |
|  |       |                                 | 362095 | positive<br>(subtype 3a)                  | (h, i)   | 1 : 405   |  |  |
|  |       |                                 | 362096 | positive<br>(subtype 3a)                  | (h)      | 1 : 15  |  |  |
| HCV<br>(RNA)<br><b>training<br/>progr.</b><br>plasma | 379   | <i>conform<br/>to<br/>B 3</i>   | 379017 | positive<br>(subtype 3a)                  | (h)      | 1 : 3 645   | <i>target values will be<br/>specified</i> | <i>target values will be<br/>specified</i> |
|  |       |                                 | 379018 | positive<br>(subtype 3a)                  | (h)      | 1 : 10 935  |  |  |
|  |       |                                 | 379019 | positive<br>(subtype 3a)                  | (h, i)   | 1 : 405   |  |  |
|  |       |                                 | 379020 | positive<br>(subtype 3a)                  | (h)      | 1 : 32 805  |  |  |

a, b, c, e, f, h: Marked samples derive from corresponding stock materials diluted in consecutive steps.

Non-marked samples derive from independent preparations.

d, g, i,: Marked samples represent overlapping samples deployed in the respective main EQA scheme (mandatory according to RiliBÄK Section B 3 and the corresponding training program.

**Please note that information on  
- target values/target value intervals for quantitative results and  
- final evaluation of the respective samples  
will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding  
EQA program.**



**Table 2 (contd.): EQA Schemes Virus Genome Detection by PCR/NAT - March 2016  
Information on sample properties**

| Program   | Group | RiliBÄK                         | Sample                              | Sample properties                         |                       |   |  |
|---|-------|---------------------------------|-------------------------------------|---|-----------------------|---|--|
|   |       |                                 |                                     | qualitative<br>(note on<br>geno-/subtype) | dilution              | Target value of all methods<br>(provisional data) |  |
|   |       |                                 |                                     |   |                       | copies/ml   | IU/ml                                      |
| HDV<br>(DNA)<br>plasma  | 400   | <i>conform<br/>to<br/>B 3</i>   | 400009                              | negative                                  | -----                 | <i>target values will<br/>be specified</i>        | <i>target values will be<br/>specified</i> |
|   |       |                                 | 400010                              | positive                                  | (j) 1 : 100           |   |  |
|   |       |                                 | 400011                              | positive                                  | (j) 1 : 1 000         |   |  |
|   |       |                                 | 400012                              | positive                                  | (j) 1 : 10            |   |  |
| HIV-1<br>(RNA)<br>spiked<br>plasma                            | 360   | <b>manda-<br/>tory:<br/>B 3</b> | 360093                              | positive (subtype B)                      | (k) 1 : 160 000       | <i>target values will<br/>be specified</i>        | <i>target values will be<br/>specified</i> |
|   |       |                                 | 360094                              | negative                                  | -----                 |   |  |
|   |       |                                 | 360095                              | positive (subtype B)                      | (k, l) 1 : 16 000 000 |   |  |
|   |       |                                 | 360096                              | positive (subtype B)                      | (k) 1 : 1 600 000     |   |  |
| HIV-1 (RNA)<br><b>training<br/>progr.</b><br>spiked<br>plasma | 382   | <i>conform<br/>to<br/>B 3</i>   | 382017                              | positive (subtype B)                      | (k) 1 : 505 964 426   | <i>target values will<br/>be specified</i>        | <i>target values will be<br/>specified</i> |
|   |       |                                 | 382018                              | positive (subtype B)                      | (k) 1 : 1 600 000 000 |   |  |
|   |       |                                 | 382019                              | positive (subtype B)                      | (k, l) 1 : 16 000 000 |   |  |
|   |       |                                 | 382020                              | positive (subtype B)                      | (k) 1 : 160 000 000   |   |  |
| JC virus<br>(DNA)<br>suspension<br>of urine                   | 394   | <i>conform<br/>to<br/>B 3</i>   | 394009 <sup>&amp;</sup> =<br>394011 | negative                                  | 1 : 1 000             | <i>target values will<br/>be specified</i>        | <i>target values will be<br/>specified</i> |
|   |       |                                 | 394010                              | positive                                  | 1 : 92                |   |  |
|   |       |                                 | 394011 <sup>&amp;</sup> =<br>394009 | negative                                  | 1 : 1 000             |   |  |
|   |       |                                 | 394012                              | positive                                  | 1 : 920               |   |  |
| Parvovirus<br>B19<br>(DNA)<br>plasma                          | 367   | <b>manda-<br/>tory:<br/>B 3</b> | 367093                              | positive                                  | (m) 1 : 300 000       | <i>target values will<br/>be specified</i>        | <i>target values will be<br/>specified</i> |
|   |       |                                 | 367094                              | negative                                  | -----                 |   |  |
|   |       |                                 | 367095                              | positive                                  | (m) 1 : 2 700 000     |   |  |
|   |       |                                 | 367096                              | positive                                  | (m) 1 : 900 000       |   |  |

j, k, m: Marked samples derive from corresponding stock materials diluted in consecutive steps.

Non-marked samples derive from independent preparations.

l: Marked samples represent overlapping samples deployed in the respective main EQA scheme (mandatory according to RiliBÄK Section B 3 and the corresponding training program.

& The samples 394009 and 394011 are identical.

**Please note that information on  
- target values/target value intervals for quantitative results and  
- final evaluation of the respective samples  
will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding  
EQA program.**

**Table 3: EQA Schemes Virus Genome Detection by PCR/NAT incl. Typing -  
March 2016  
Information on sample properties**

| Program   | Group | RiliBÄK   | Sample                       | Sample properties |  |         |   |
|---|-------|---|------------------------------|-------------------|--|---------|---|
|   |       |   |                              | qualitative       | Target value of all methods copies/ml  | species | type (note on dilution)                       |
| Dengue viruses (RNA)<br>cell lysates                                | 369   | <i>conform to B 3</i>                                   | 369017                       | positive          | <i>target values will be specified</i> | ----    | DENV-2 (inactivated)<br>1 : 50 diluted        |
|   |       |   | 369018                       | positive          |  | ----    | DENV-1 (inactivated)<br>1 : 25 diluted        |
|   |       |   | 369019                       | negative          |  | ----    | ----  |
|   |       |   | 369020                       | positive          |  | ----    | DENV-4 (inactivated)<br>1 : 10 diluted        |
| Enteroviruses-PCR/<br>Cultivation and Typing<br>suspension of feces | 374   | <i>according to RKI-Enterovirus-Surveillance Progr.</i> | 374013                       | positiv           | <i>target values will be specified</i> | ----    | Poliovirus type 3 (Sabin)<br>vaccine strain   |
|   |       |   | 374014                       | positiv           |  | ----    | Coxsackievirus B3                             |
|   |       |   | 374015                       | positiv           |  | ----    | Coxsackievirus A4                             |
|   |       |   | 374016                       | positiv           |  | ----    | Poliovirus type 1 (Sabin)<br>vaccine strain   |
|   |       |   | 374017                       | positiv           |  | ----    | Echovirus 6                                   |
| Norovirus (RNA)<br>suspension of feces                              | 381   | <i>conform to B 3</i>                                   | 381025                       | negative          | <i>target values will be specified</i> | ----    | 1 : 200 diluted                               |
|   |       |   | 381026                       | positive          |  | ----    | genogroup I<br>1 : 740 diluted                |
|   |       |   | 381027 <sup>§</sup> = 381028 | positive          |  | ----    | genogroup II<br>1 : 220 diluted               |
|   |       |   | 381028 <sup>§</sup> = 381027 | positive          |  | ----    | genogroup II<br>1 : 220 diluted               |
| Para-influenza viruses (RNA)<br>cell lysates                        | 388   | <i>conform to B 3</i>                                   | 388017                       | positive          | <i>target values will be specified</i> | ----    | PIV-3<br>1 : 1 000 diluted                    |
|   |       |   | 388018                       | negative          |  | ----    | ----  |
|   |       |   | 388019                       | positive          |  | ----    | PIV-2<br>1 : 50 diluted (n)                   |
|   |       |   | 388020                       | positive          |  | ----    | PIV-3<br>1 : 500 diluted (n)                  |
| West Nile virus (RNA)<br>cell lysates                               | 391   | <i>conform to B 3</i>                                   | 391023                       | positive          | <i>target values will be specified</i> | ----    | WNV-2 (inactivated)<br>1 : 3 diluted (o)      |
|   |       |   | 391024                       | positive          |  | ----    | WNV-1 (inactivated)<br>1 : 300 diluted (p)    |
|   |       |   | 391025                       | positive          |  | ----    | WNV-1 (inactivated)<br>1 : 30 000 diluted (p) |
|   |       |   | 391026                       | positive          |  | ----    | WNV-2 (inactivated)<br>1 : 30 diluted (o)     |
|   |       |   | 391027                       | positive          |  | ----    | WNV-2 (inactivated)<br>1 : 300 000 diluted    |
|   |       |   | 391028                       | negative          |  | ----    | ----  |

\* The Special EQA program in accordance with the RKI-entero surveillance programm - virus detection - Enterovirus - PCR / Cultivation and Typing (374) is performed in cooperation with Nationales Referenzzentrum für Poliomyelitis und Enteroviren, Regionales Referenzlabor der WHO/EURO für Poliomyelitis, Robert Koch-Institut, Berlin, Dr. Sabine Diedrich.

n, o, p: Marked samples derive from corresponding stock materials diluted in consecutive steps.

Non-marked samples derive from independent preparations.

§ The samples 381027 and 381028 are identical.

**Please note that information on  
- target values/target value intervals for quantitative results and  
- final evaluation of the respective samples  
will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding EQA program.**

**Table 3 (contd.): EQA Schemes Virus Genome Detection incl. Typing  
March 2016  
Information on sample properties**

| Program  | Group | RiliBÄK           | Sample | Sample properties and results considered as "correct" (target values)  |  |  |
|--|-------|-------------------|--------|--|--|--|
|  |       |                   |        | type/subtype   | strain   | origin   |
| Influenza A- und B-viruses*<br>inclusive<br>influenza A(H1N1) pdm09 virus<br>and<br>avian influenza A virus (different subtypes)<br><br>(genome/antigen) | 370*  | mandatory:<br>B 3 | 370071 | positive<br>for<br>seasonal influenza A(H3N2) virus  | A/Switzerland/9715293/<br>2013<br>(vaccine strain) | infected MDCK-cells (lysate)<br>(1 : 200 diluted)  |
|  |       |                   | 370072 | negative   | -----  | non-infected MDCK cells (lysate)                   |
|  |       |                   | 370073 | positive<br>for<br>seasonal influenza B virus  | B/Phuket/3073/2013<br>(vaccine strain)             | infected MDCK-cells (lysate)<br>(1 : 100 diluted)  |
|  |       |                   | 370074 | positive<br>for<br>avian Influenza A(H5N8) virus<br>(accepted target value<br>for rapid tests for the detection of<br>influenza A virus antigen:<br>positive / borderline) <sup>§</sup>  | A/Turkey/Germany<br>R2485+86/2014                  | allantoic fluid (inactivated)<br>(1 : 160 diluted) |
|  |       |                   | 370075 | positive<br>for<br>seasonal influenza B virus  | B/Brisbane/60/2008<br>(vaccine strain)             | infected MDCK-cells (lysate)<br>(1 : 17 diluted)   |
|  |       |                   | 370076 | positive<br>for<br>Influenza A(H1N1) pdm09- virus<br>(accepted target value<br>for rapid tests for the detection of<br>influenza A virus antigen:<br>positive / borderline) <sup>§</sup> | A/California/7/2009/<br>(vaccine strain)           | infected MDCK-cells (lysate)<br>(1 : 150 diluted)  |

\* The EQA program for influenza A and B viruses, incl. influenza A(H1N1) pdm09 virus and avian influenza A virus (different subtypes) (370), is performed in cooperation with Nationales Referenzzentrum für Influenza, Robert Koch-Institut, Berlin, Dr. Brunhilde Schweiger and Nationales Referenzlabor für Aviäre Influenza, Bundesforschungsinstitut für Tiergesundheit, Friedrich-Loeffler-Institut, Insel Riems, Prof. Dr. Timm C. Harder.

§ For samples 370074 and 370076, the reporting of "borderline" in test category 30 (Antigen detection of influenza A virus) was accepted as additional correct result for tests for antigen detection of influenza A virus (in general rapid tests). Considering also the result "borderline" ensured that these positive samples would not have been misinterpreted as negative.

**Please note that information on  
- target values/target value intervals for quantitative results and  
- final evaluation of the respective samples  
will be specified in the forthcoming pre-evaluation, the participation documents as well as the reports of the corresponding EQA program.**