altona DIAGNOSTICS

Instructions for Use

RealStar®
Parvovirus B19 PCR Kit 1.0

01/2017 EN

RealStar®

RealStar®

Parvovirus B19 PCR Kit 1.0

For use with

m2000rt (Abbott Diagnostics)

Mx 3005P™ QPCR System (Stratagene)

VERSANT® kPCR Molecular System AD (Siemens Healthcare)

ABI Prism® 7500 SDS (Applied Biosystems)

ABI Prism® 7500 Fast SDS (Applied Biosystems)

Rotor-Gene® 6000 (Corbett Research)

Rotor-Gene® Q5/6 plex Platform (QIAGEN)

CFX96™ Real-Time PCR Detection System (Bio-Rad)

LightCycler® 480 Instrument II (Roche)

CE

IVD

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Content

1. Intended Use

The RealStar® Parvovirus B19 PCR Kit 1.0 is an *in vitro* diagnostic test, based on real-time PCR technology, for the detection and quantification of parvovirus B19 specific DNA.

2. Kit Components

Lid Color	Component	Number of Vials	Volume [µl/Vial]
Blue	Master A	8	60
Purple	Master B	8	180
Green	Internal Control	1	1000
Red	QS1-4*	4	250
White	Water (PCR grade)	1	500

* The RealStar® Parvovirus B19 PCR Kit 1.0 contains Quantification Standards (QS) at four different concentrations (see Chapter 6. Product Description)

3. Storage

- The RealStar® Parvovirus B19 PCR Kit 1.0 is shipped on dry ice. The components of the kit should arrive frozen. If one or more components are not frozen upon receipt, or if tubes have been compromised during shipment, contact altona Diagnostics GmbH for assistance.
- All components should be stored between -25°C and -15°C upon arrival.
- Repeated thawing and freezing of Master reagents (more than twice) should be avoided, as this might affect the performance of the assay. The reagents should be frozen in aliquots, if they are to be used intermittently.
- Storage between +2°C and +8°C should not exceed a period of two hours.
- Protect Master A and Master B from light.

4. Material and Devices required but not provided

- Appropriate real-time PCR instrument (see chapter 6.1 Real-Time PCR Instruments)
- Appropriate nucleic acid extraction system or kit (see chapter 8.1 Sample Preparation)
- Desktop centrifuge with a rotor for 2 ml reaction tubes
- Centrifuge with a rotor for microtiter plates, if using 96 well reaction plates
- Vortex mixer
- Appropriate 96 well reaction plates or reaction tubes with corresponding (optical) closing material
- Pipettes (adjustable)
- Pipette tips with filters (disposable)
- Powder-free gloves (disposable)

NOTE	
	***Please ensure that all instruments used have been installed, calibrated, checked and maintained according to the manufacturer´s instructions and recommendations.***
	***It is highly recommended to use the 72-well rotor with the appropriate 0.1 ml reaction tubes, if using the Rotor-Gene® 6000 (Corbett Research) or the Rotor-Gene® Q 5/6 plex (QIAGEN).***

5. Background Information

Human parvovirus B19 (parvovirus B19), also called *Erythrovirus B19*, was the first known human virus in the family of *Parvovirinae* and the genus *Erythrovirus*. The virus is a non-enveloped, icosahedral virus that contains a single-stranded linear DNA genome.

Parvovirus B19 causes a childhood rash called fifth disease or erythema infectiosum which is commonly called slapped cheek syndrome. Parvovirus B19 is a major cause of a plastic crisis in patients with hemolytic anemia. Severe fetal complications can be observed, especially following maternal infections during the second and third trimesters.

Three distinct genotypes (Genotype I-III) of *Human parvovirus B19* have been identified, varying by up to 15% in nucleotide identity. Based upon sequence analysis and biological properties, the International Committee on Taxonomy of Viruses has classified representatives of the three genotypes as species of *Human parvovirus B19*. In Europe, regulatory requirements specify that plasma pools used in the production of anti-D immunoglobulin and plasma treated for virus inactivation are tested for levels of parvovirus B19 DNA. Such plasma pools must not exceed a threshold concentration of 10 IU/µl for parvovirus B19 DNA, as defined by the WHO IS (2nd IS NIBSC code 99/802).

6. Product Description

The RealStar® Parvovirus B19 PCR Kit 1.0 is an *in vitro* diagnostic test, based on real-time PCR technology, for the detection and quantification of parvovirus B19 specific DNA.

The assay includes a heterologous amplification system (Internal Control) to identify possible PCR inhibition and to confirm the integrity of the reagents of the kit.

Real-time PCR technology utilizes polymerase chain reaction (PCR) for the amplification of specific target sequences and target specific probes for the detection of the amplified DNA. The probes are labelled with fluorescent reporter and quencher dyes.

Probes specific for parvovirus B19 DNA are labelled with the fluorophore FAM™. The probe specific for the Internal Control (IC) is labelled with the fluorophore JOE™.

Using probes linked to distinguishable dyes enables the parallel detection of parvovirus B19 specific DNA and the Internal Control in corresponding detector channels of the real-time PCR instrument.

The test consists of two processes in a single tube assay:

- PCR amplification of target DNA and Internal Control
- Simultaneous detection of PCR amplicons by fluorescent dye labelled probes

The RealStar® Parvovirus B19 PCR Kit 1.0 consists of:

- Two Master reagents (Master A and Master B)
- Internal Control (IC)
- Four Quantification Standards (QS1 - QS4)
- PCR grade water

Master A and Master B contain all components (PCR buffer, DNA polymerase, magnesium salt, primers and probes) to allow PCR mediated amplification and detection of parvovirus B19 specific DNA and Internal Control in one reaction setup.

The Quantification Standards contain standardized concentrations of parvovirus B19 specific DNA. These Quantification Standards were calibrated against the 2nd World Health Organization International Standard for Parvovirus B19 for Nucleic Acid Amplification Techniques (NAT) (NIBSC code: 99/802). The Quantification Standards can be used individually as positive controls, or together to generate a **standard curve**, which can be used to determine the concentration of parvovirus B19 specific DNA in a sample.

The Quantification Standards have the following concentrations:

Quantification Standard	Concentration [IU/µl]
QS1	1.00E+04
QS2	1.00E+03
QS3	1.00E+02
QS4	1.00E+01

6.1 Real-Time PCR Instruments

The RealStar® Parvovirus B19 PCR Kit 1.0 was developed and validated to be used with the following real-time PCR instruments:

- m2000rt (Abbott Diagnostics)
- Mx 3005P™ QPCR System (Stratagene)
- VERSANT® kPCR Molecular System AD (Siemens Healthcare)
- ABI Prism® 7500 SDS (Applied Biosystems)
- ABI Prism® 7500 Fast SDS (Applied Biosystems)
- Rotor-Gene® 6000 (Corbett Research)
- Rotor-Gene® Q5/6 plex Platform (QIAGEN)
- CFX96™ Real-Time PCR Detection System (Bio-Rad)
- LightCycler® 480 Instrument II (Roche)

6.2 Sample Types

The following sample types have been validated with the RealStar® Parvovirus B19 PCR Kit 1.0:

- Human EDTA plasma

If an appropriate nucleic acid extraction procedure is applied additional sample types can be used along with the RealStar® Parvovirus B19 PCR Kit 1.0. The suitability of the nucleic acid extraction procedure has to be validated by the user.

7. Warnings and Precautions

Read the Instructions for Use carefully before using the product.

- Before first use check the product and its components for:
  - Integrity
  - Completeness with respect to number, type and filling (see chapter 2. Kit Components)
  - Correct labelling
  - Frozenness upon arrival
- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.
- Specimens should always be treated as infectious and/or biohazardous in accordance with safe laboratory procedures.
- Wear protective disposable powder-free gloves, a laboratory coat and eye protection when handling specimens.
- Avoid microbial and nuclease (DNase/RNase) contamination of the specimens and the components of the kit.
- Always use DNase/RNase-free disposable pipette tips with aerosol barriers.
- Always wear protective disposable powder-free gloves when handling kit components.

- Use separated and segregated working areas for (i) sample preparation, (ii) reaction setup and (iii) amplification/detection activities. The workflow in the laboratory should proceed in unidirectional manner. Always wear disposable gloves in each area and change them before entering a different area.
- Dedicate supplies and equipment to the separate working areas and do not move them from one area to another.
- Store positive and/or potentially positive material separated from all other components of the kit.
- Do not open the reaction tubes/plates post amplification, to avoid contamination with amplicons.
- Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations.
- Do not autoclave reaction tubes after the PCR, since this will not degrade the amplified nucleic acid and will bear the risk to contaminate the laboratory area.
- Do not use components of the kit that have passed their expiration date.
- Discard sample and assay waste according to your local safety regulations.

8. Procedure

8.1 Sample Preparation

Extracted DNA is the starting material for the RealStar® Parvovirus B19 PCR Kit 1.0.

The quality of the extracted DNA has a profound impact on the performance of the entire test system. It has to be ensured that the system used for nucleic acid extraction is compatible with real-time PCR technology. The following kits and systems are suitable for nucleic acid extraction:

- QIAamp® DNA Mini Kit (QIAGEN)
- QIAsymphony® (QIAGEN)
- NucliSENS® easyMag® (bioMérieux)

- MagNA Pure 96 System (Roche)
- m2000sp (Abbott)
- Maxwell® 16 IVD Instrument (Promega)
- VERSANT® kPCR Molecular System SP (Siemens Healthcare)

Alternative nucleic acid extraction systems and kits might also be appropriate. The suitability of the nucleic acid extraction procedure for use with RealStar® Parvovirus B19 PCR Kit 1.0 has to be validated by the user.

If using a spin column based sample preparation procedure including washing buffers containing ethanol, it is highly recommended to perform an additional centrifugation step for 10 min at approximately 17000 x g (~ 13000 rpm), using a new collection tube, prior to the elution of the nucleic acid.

CAUTION	
	***If your sample preparation system is using washing buffers containing ethanol, make sure to eliminate any traces of ethanol prior to elution of the nucleic acid. Ethanol is a strong inhibitor of real-time PCR.***
	***The use of carrier RNA is crucial for extraction efficiency and stability of the extracted nucleic acid.***

For additional information and technical support regarding pre-treatment and sample preparation please contact our Technical Support (see chapter 14. Technical Assistance).

8.2 Master Mix Setup

All reagents and samples should be thawed completely, mixed (by pipetting or gentle vortexing) and centrifuged briefly before use.

The RealStar® Parvovirus B19 PCR Kit 1.0 contains a heterologous Internal Control

(IC), which can either be used as a PCR inhibition control or as a control of the sample preparation procedure (nucleic acid extraction) and as a PCR inhibition control.

► If the IC is used as a PCR inhibition control, but not as a control for the sample preparation procedure, set up the Master Mix according to the following pipetting scheme:

Number of Reactions (rxns)	1	12
Master A	5 µl	60 µl
Master B	15 µl	180 µl
Internal Control	1 µl	12 µl
Volume Master Mix	**21 µl**	**252 µl**

► If the IC is used as a control for the sample preparation procedure and as a PCR inhibition control, add the IC during the nucleic acid extraction procedure.

► No matter which method/system is used for nucleic acid extraction, the IC **must not** be added directly to the specimen. The IC should always be added to the specimen/lysis buffer mixture. The volume of the IC which has to be added, always and only depends on the elution volume. It represents 10% of the elution volume. For instance, if the nucleic acid is going to be eluted in 60 µl of elution buffer or water, 6 µl of IC per sample must be added into the specimen/lysis buffer mixture.

► If the IC was added during the sample preparation procedure, set up the Master Mix according to the following pipetting scheme:

Number of Reactions (rxns)	1	12
Master A	5 µl	60 µl
Master B	15 µl	180 µl
Volume Master Mix	**20 µl**	**240 µl**

CAUTION

If the IC (Internal Control) was added during the sample preparation procedure, at least the negative control must include the IC.

No matter which method/system is used for nucleic acid extraction, never add the IC directly to the specimen.

8.3 Reaction Setup

- ► Pipette 20 µl of the Master Mix into each required well of an appropriate optical 96-well reaction plate or an appropriate optical reaction tube.
- ► Add 10 µl of the sample (eluate from the nucleic acid extraction) or 10 µl of the controls (Quantification Standard, Positive or Negative Control).

Reaction Setup	
Master Mix	20 µl
Sample or Control	10 µl
Total Volume	**30 µl**

- ► Make sure that at least one Positive (QS) and one Negative Control is used per run.
- ► For quantification purposes all Quantification Standards (QS1 to QS4) should be used.
- ► Thoroughly mix the samples and controls with the Master Mix by pipetting up and down.
- ► Close the 96-well reaction plate with appropriate lids or optical adhesive film and the reaction tubes with appropriate lids.
- ► Centrifuge the 96-well reaction plate in a centrifuge with a microtiter plate rotor for 30 seconds at approximately 1000 x g (~ 3000 rpm).

9. Programming the Real-Time PCR Instrument

For basic information regarding the setup and programming of the different real-time PCR instruments, please refer to the user manual of the respective instrument.

For detailed programming instructions regarding the use of the RealStar® Parvovirus B19 PCR Kit 1.0 on specific real-time PCR instruments please contact our Technical Support (see chapter 14. Technical Assistance).

9.1 Settings

► Define the following settings:

Settings	
Reaction Volume	30 µl
Ramp Rate	Default
Passive Reference	ROX™

9.2 Fluorescence Detectors (Dyes)

► Define the fluorescence detectors (dyes):

Target	Detector Name	Reporter	Quencher
Parvovirus B19 specific DNA	Parvovirus B19	FAM™	(None)
Internal Control (IC)	IC	JOE™	(None)

9.3 Temperature Profile and Dye Acquisition

► Define the temperature profile and dye acquisition:

	Stage	Cycle Repeats	Acquisition	Temperature [°C]	Time [min:sec]
Denaturation	Hold	1	-	95	10:00
Amplification	Cycling	45	-	95	00:15
			yes	58	01:00

10. Data Analysis

For basic information regarding data analysis on specific real-time PCR instruments, please refer to the user manual of the respective instrument.

For detailed instructions regarding the analysis of the data generated with the RealStar® Parvovirus B19 PCR Kit 1.0 on different real-time PCR instruments please contact our Technical Support (see chapter 14. Technical Assistance).

10.1 Validity of Diagnostic Test Runs

10.1.1 Valid Diagnostic Test Run (qualitative)

A **qualitative** diagnostic test run is **valid**, if the following control conditions are met:

Control ID	Detection Channel	
	FAM™	JOE™
Positive Control (QS)	+	+/-*
Negative Control	-	+

* The presence or absence of a signal in the JOE™ channel is not relevant for the validity of the test run.

10.1.2 Invalid Diagnostic Test Run (qualitative)

A **qualitative** diagnostic test run is **invalid**, (i) if the run has not been completed or (ii) if any of the control conditions for a **valid** diagnostic test run are not met.

In case of an **invalid** diagnostic test run, repeat testing by using the remaining purified nucleic acids or start from the original samples again.

10.1.3 Valid Diagnostic Test Run (quantitative)

A **quantitative** diagnostic test run is **valid**, if all control conditions for a **valid qualitative** diagnostic test run are met [see chapter 10.1.1 Valid Diagnostic Test Run (qualitative)]. The **quantification** results are **valid** if the generated **standard curve** reaches the following control parameter value:

Control Parameter	Valid Value
R square (R^2)	≥ 0.98

NOTE

Not all real-time PCR instruments display the R square (R^2) value. For detailed information, please refer to the user manual of the respective instrument.

10.1.4 Invalid Diagnostic Test Run (quantitative)

A **quantitative** diagnostic test run is **invalid**, (i) if the run has not been completed or (ii) if any of the control conditions for a **valid quantitative** diagnostic test run are not met.

In case of an **invalid** diagnostic test run, repeat testing by using the remaining purified nucleic acids or start from the original samples again.

10.2 Interpretation of Results

10.2.1 Qualitative Analysis

Detection Channel		Result Interpretation
FAM™	JOE™	
+	+*	Parvovirus B19 specific DNA detected.
-	+	No parvovirus B19 specific DNA detected. Sample does not contain detectable amounts of parvovirus B19 specific DNA.
-	-	PCR inhibition or reagent failure. Repeat testing from original sample or collect and test a new sample.

* Detection of the Internal Control in the JOE™ detection channel is not required for positive results in the FAM™ detection channel. A high parvovirus B19 DNA load in the sample can lead to a reduced or absent Internal Control signal.

10.2.2 Quantitative Analysis

The RealStar® Parvovirus B19 PCR Kit 1.0 includes four Quantification Standards (QS). In order to generate a **standard curve** for quantitative analysis, these have to be defined as **standards** with appropriate concentrations (see chapter 6. Product Description). Using **standards** of known concentrations a standard curve for quantitative analysis can be generated.

$$C_t = m \cdot \log (N_0) + b$$

C_t = Threshold Cycle
m = Slope
N_0 = Initial Concentration
b = Intercept

Derived from the standard curve positive samples of unknown concentrations can be quantified.

$$N_0 = 10^{(C_t - b)/m}$$

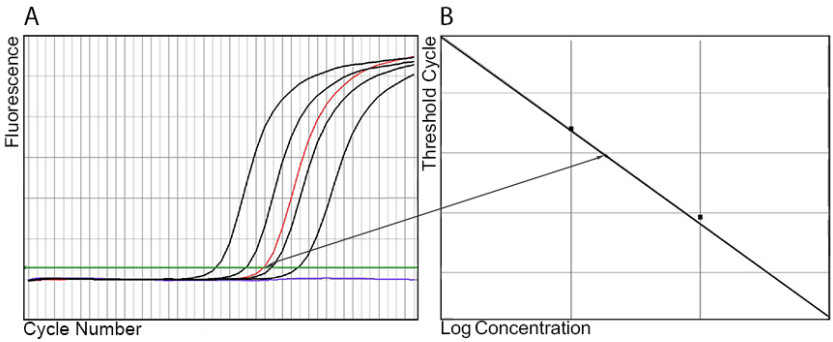

Figure 1: Quantification Standards (black), a positive (red) and a negative sample (blue) displayed in the Amplification Plot [**A**] and Standard Curve analysis [**B**]

NOTE

The concentration of the "Sample" is displayed in IU/µl and refers to the concentration in the eluate.

To determine the **viral load of the original sample**, the following formula has to be applied:

$$\text{Viral load (}\mathbf{Sample}\text{) [IU/ml]} = \frac{\text{Volume (}\mathbf{Eluate}\text{) [µl]} \cdot \text{Viral load (}\mathbf{Eluate}\text{) [IU/µl]}}{\text{Sample Input [ml]}}$$

11. Performance Evaluation

Performance evaluation of the RealStar® Parvovirus B19 PCR Kit 1.0 was done using quantified parvovirus B19 DNA calibrated against the 2nd WHO International Standard for parvovirus B19 (NIBSC code: 99/802).

11.1 Analytical Sensitivity

The analytical sensitivity of the RealStar® Parvovirus B19 PCR Kit 1.0 is defined as the concentration (IU/µl of the eluate) of parvovirus B19 specific DNA molecules that can be detected with a positivity rate of 95%. The analytical sensitivity was determined by analysis of dilution series of quantified parvovirus B19 specific DNA.

Table 1: PCR results used for the calculation of the analytical sensitivity with respect to the detection of parvovirus B19 specific DNA

Input Conc. [IU/µl]	Number of Replicates	Number of Positives	Hit Rate [%]
10.000	16	16	100
3.162	16	16	100
1.000	16	16	100
0.316	16	15	94
0.210	8	5	63
0.140	8	4	50
0.090	8	4	50
0.060	8	3	38
0.030	16	0	0
0.010	16	0	0

The analytical sensitivity of the RealStar® Parvovirus B19 PCR Kit 1.0 was determined by Probit analysis:

- For the detection of parvovirus B19 specific DNA, the analytical sensitivity is 0.41 IU/µl [95% confidence interval (CI): 0.27-0.90 IU/µl]

11.2 Analytical Specificity

The analytical specificity of the RealStar® Parvovirus B19 PCR Kit 1.0 is ensured by the thorough selection of the oligonucleotides (primers and probes). The oligonucleotides were checked by sequence comparison analysis against publicly available sequences to ensure that all relevant parvovirus B19 genotypes will be detected.

The analytical specificity of the RealStar® Parvovirus B19 PCR Kit 1.0 was evaluated by testing a panel of genomic DNA/RNA extracted from other blood born viruses or pathogens significant in immunocompromised patients.

The RealStar® Parvovirus B19 PCR Kit 1.0 did not cross-react with any of the following pathogens:

- BK virus
- Cytomegalovirus
- Epstein-Barr virus
- Hepatitis A virus
- Hepatitis B virus
- Hepatitis C virus
- Herpes simplex virus 1
- Herpes simplex virus 2
- Human herpesvirus 6A
- Human herpesvirus 6B
- Human herpesvirus 7
- Human herpesvirus 8
- Human immunodeficiency virus 1
- JC virus
- Varicella-zoster virus

11.3 Linear Range

The linear range of the RealStar® Parvovirus B19 PCR Kit 1.0 was evaluated by analysing a logarithmic dilution series of parvovirus B19 DNA using concentrations ranging from 1.00E+09 to 1.00E+00 IU/µl. Each dilution was analysed in eight replicates.

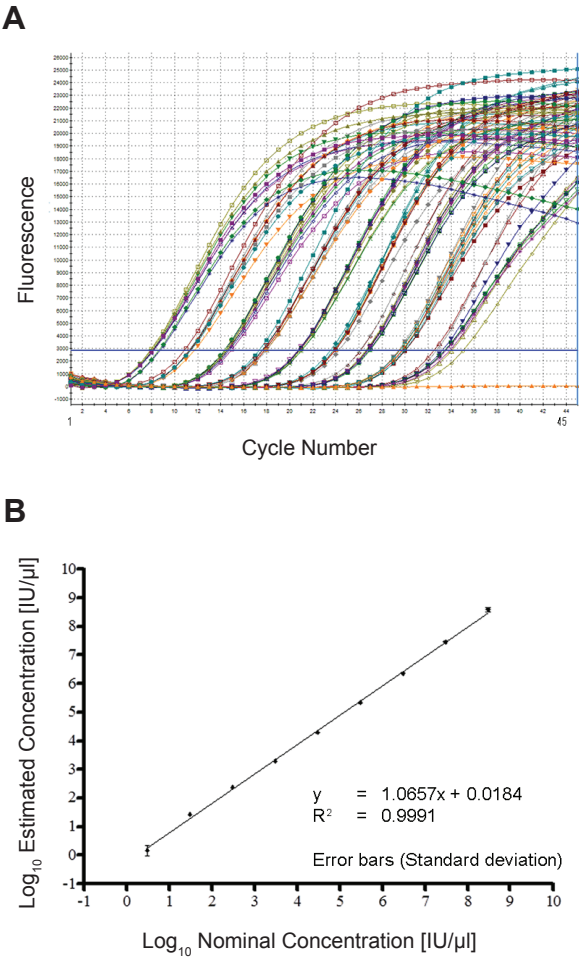

Figure 2: Amplification curves [**A**] and linear regression [**B**] of an analysed dilution series of parvovirus B19 specific DNA

The linear range of the RealStar® Parvovirus B19 PCR Kit 1.0 extends over an interval of at least **eight** orders of magnitude.

11.4 Precision

Precision of the RealStar® Parvovirus B19 PCR Kit 1.0 was determined as intra-assay variability (variability within one experiment), inter-assay variability (variability between different experiments) and inter-lot variability (variability between different production lots). Total variability was calculated by combining the three analyses.

Variability data are expressed in terms of standard deviation and coefficient of variation. The data are based on quantification analysis of defined concentrations of parvovirus B19 specific DNA and on threshold cycle (C_t) value in terms of the Internal Control. At least six replicates per sample were analysed for intra-assay, inter-assay and inter-lot variability.

Table 2: Precision data for the detection of parvovirus B19 specific DNA

Parvovirus B19	Average Conc. [IU/µl]	Standard Deviation	Coefficient of Variation [%]
Intra-Assay Variability	219.36	5.42	2.47
Inter-Assay Variability	215.66	8.67	4.02
Inter-Lot Variability	211.65	10.47	4.95
Total Variability	211.75	10.07	4.75

Table 3: Precision data for the detection of the Internal Control

Internal Control	Average Threshold Cycle (C_t)	Standard Deviation	Coefficient of Variation [%]
Intra-Assay Variability	24.90	0.09	0.36
Inter-Assay Variability	24.75	0.13	0.54
Inter-Lot Variability	24.86	0.11	0.46
Total Variability	24.80	0.14	0.56

11.5 Diagnostic Evaluation

Diagnostic specificity and sensitivity of the RealStar® Parvovirus B19 PCR Kit 1.0 was evaluated by analysing 115 specimens. The nucleic acids were extracted using the QIAamp® DNA Mini Kit (QIAGEN). The samples were analysed on an ABI Prism® 7500 SDS (Applied Biosystems) and on a Rotor-Gene® 6000 (Corbett Research).

Table 4: Results of the diagnostic evaluation of RealStar® Parvovirus B19 PCR Kit 1.0

		RealStar® Parvovirus B19 PCR Kit 1.0	
		+	-
Pretested	+	93	3
	-	1	18

12. Limitations

- Strict compliance with the Instructions for Use is required for optimal results.
- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.
- Good laboratory practice is essential for proper performance of this assay. Extreme care should be taken to preserve the purity of the components of the kit and reaction setups. All reagents should be closely monitored for impurity and contamination. Any suspicious reagents should be discarded.
- Appropriate specimen collection, transport, storage and processing procedures are required for the optimal performance of this test.

- This assay must not be used on the specimen directly. Appropriate nucleic acid extraction methods have to be conducted prior to using this assay.
- The presence of PCR inhibitors (e.g. heparin) may cause underquantification, false negative or invalid results.
- Potential mutations within the target regions of the parvovirus B19 genome covered by the primers and/or probes used in the kit may result in underquantification and/or failure to detect the presence of the pathogens.
- As with any diagnostic test, results of the RealStar® Parvovirus B19 PCR Kit 1.0 need to be interpreted in consideration of all clinical and laboratory findings.

13. Quality Control

In accordance with the altona Diagnostics GmbH EN ISO 13485-certified Quality Management System, each lot of RealStar® Parvovirus B19 PCR Kit 1.0 is tested against predetermined specifications to ensure consistent product quality.

14. Technical Assistance

For technical advice, please contact our Technical Support:

e-mail: **support@altona-diagnostics.com**

phone: **+49-(0)40-5480676-0**

15. Literature

Versalovic, James, Carroll, Karen C.,Funke, Guido, Jorgensen, James H., Landry, Marie Louise and David W. Warnock (ed). Manual of Clinical Microbiology. 10th Edition. ASM Press, 2011.

Cohen, Jonathan, Powderly, William G, and Steven M Opal. Infectious Diseases, Third Edition. Mosby, 2010.

16. Trademarks and Disclaimers

RealStar® (altona Diagnostics); ABI Prism® (Applied Biosystems); ATCC® (American Type Culture Collection); CFX96™ (Bio-Rad); Cy® (GE Healthcare); FAM™, JOE™, ROX™ (Life Technologies); LightCycler® (Roche); SmartCycler® (Cepheid); Maxwell® (Promega); Mx 3005P™ (Stratagene); NucliSENS®, easyMag® (bioMérieux); Rotor-Gene®, QIAamp®, MinElute®, QIAsymphony® (QIAGEN); VERSANT® (Siemens Healthcare).

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The RealStar® Parvovirus B19 PCR Kit 1.0 is a CE-marked diagnostic kit according to the European *in vitro* diagnostic directive 98/79/EC.

Product not licensed with Health Canada and not FDA cleared or approved.

Not available in all countries.

17. Explanation of Symbols

Symbol	Explanation
IVD	*In vitro* diagnostic medical device
LOT	Batch code
CAP	Cap color
REF	Product number
CONT	Content
NUM	Number
COMP	Component
GTIN	Global trade identification number
	Consult instructions for use
	Contains sufficient for “n” tests/reactions (rxns)
	Temperature limit
	Use-by date
	Manufacturer
	Caution
	Note
	Version

Notes:

always a drop ahead.

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