Section 1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

1.1 Product identifier

Product name: **FastCheck**POC® 20
Point of care test for the determination of specific IgE (human)

Product number(s): 79750002, 79750004, 79750009, 79750010, 79750011

1.2 Relevant identified uses of the product and uses advised against

FastCheckPOC® 20 is a semi-quantitative enzyme immunoassay for the parallel measurement of allergen-specific IgE antibodies to 20 allergens and allergen mixtures in heparinized, Na-EDTA or citrate-treated human capillary whole blood, venous whole blood or human plasma, and human serum. *in-vitro* diagnostic. It is to be carried out by healthcare professionals experienced in the use of *in-vitro* diagnostic methods. It is not suitable for self-testing and not for veterinary use. Do not use reagents for purposes other than those specified.

1.3 Details of the supplier of the data sheet

Company:

DST Diagnostische Systeme & Technologien GmbH
Gueterbahnhofstrasse 16
19059 Schwerin
Germany
Phone: +49 (0)385/303 48-0
Fax: +49 (0)385/303 48-499
E-Mail address: info@dst-diagnostic.com

1.4 Emergency telephone number

For further enquires please call the following telephone number: +49 (0)385/30348-0
(technical service department, office hours: 8:00-16:00).

Section 2. HAZARDS IDENTIFICATION

2.1 Classification

Produkt: This product is not classified as dangerous according to Regulation (EC) No. 1272/2008. It is not a substance or a mixture.

Substances/mixtures: The concentrations of the substances contained in the liquid components are below limits stipulated in Regulation (EC) no. 1272/2008 and are therefore not classified as hazardous.

The most important harmful physico-chemical effects, effects on human health and the environment
None.

2.2 Label elements

Not classified according to (EC) No. 1272/2008 (CLP).

2.3 Other hazards

The product, incl. all ingredients of the liquid reagents, does not meet the criteria for classification as PBT (persistent, bio accumulative and toxic at the same time) or vPvB (very persistent and very high bioaccumulation).
Human blood samples/developed FastCheckPOC®20 test cassettes can be infectious.
The colour reagent reacts colour intensively under the influence of light.

Refer to protective measures listed in sections 7, 8 and 13.

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

Not applicable.

3.2 Product

The FastCheckPOC® 20 test kit is a product and not a chemical substance/mixture.

Each test kit of FastCheckPOC® 20 is packaged in a sealed box.

The kit contains:
- Package leaflet/Instruction for use
- Evaluation sheet
- Test cassette
    - cassette contains membrane strips with single extracts, extract mixtures and controls (exact occupancy see evaluation sheet)
    - dry bag
    - in a transparent clip-bag
- Blood sampling pouch
    - transparent clip-bag with band-aid, alcohol wipe, gauze/absorbent pad, sterile safety lancet, plastic syringe and blood-sampling capillary with Heparin
- Dry bag
- Liquid reagents:
    - Sample dilutor (with red lid) – DILUT
    - Washing solution (with blue lid) – WASH
    - Antibody solution 1 (with transparent lid) – Ab1
    - Antibody solution 2 (with yellow lid) – Ab2
    - Colour reagent (with white lid) – COLR
    - Stop buffer (with green lid) – STOP

Additional material required:
- Disposable gloves
- Timer
- Sufficient lightning
- For venous blood or plasma
    - Equipment for venous blood collection
    - Heparinized blood collection tubes
    - Laboratory pipette
    - If necessary a centrifuge for serum/plasma collection

3.3 Mixture

All liquid components are mixtures. The concentrations of the substances contained in the liquid components are below limits stipulated in Regulation (EC) No. 1272/2008.

Ingredient	Concentration	CAS No.	EC No.	Risks (according to Regulation (EC) no. 1272/2008
2-Methyl-2H-isothiazol-3-one	< 0.1 %	2682-20-4	220-239-6	Acute Toxicity, Cat. 3, H302 Acute Toxicity, Cat. 4, H331 Skin corrosion, Cat.1B, H314 Skin sensitisation, Cat. 1, H317 STOT (single exposure), Cat. 3, H335 Hazardous to the aquatic environment — Acute, Cat. 1, H400
Digoxigenin	< 0.1%	1672-46-4	216-806-2	Acute Toxicity, Cat. 1, swallow, H300 Acute Toxicity, Cat. 2, skin, H310 Acute Toxicity, Cat. 1, inhalation, H330
Hydrochloric acid	< 0.1%	7647-01-0	231-595-7	Corrosive against metals, Cat. 1, H290 Skin corrosion, Cat. 1B, H314 Skin irritation, Cat. 2, H315 Eye irritation, Cat. 2, H319 STOT (single exposure), Cat. 3, H335
Isopropyl alcohol	< 0.1%	67-63-0	200-661-7	Flammable liquids, Cat. 2; H225 Eye irritation, Cat. 2, H319 STOT (single exposure), Cat. 3; H336
Nitroblue tetrazolium	< 1 %	298-83-9	206-067-4	Acute Toxicity, Cat. 4, H302
Sodium azide	< 0.1 %	26628-22-8	247-852-1	Acute Toxicity, Cat. 2, swallow, H300 Acute Toxicity, Cat. 2, skin, H310 STOT (repeated exposure), Cat. 2 (brain), H373 Hazardous to the aquatic environment — Acute, Cat. 1, H400 Hazardous to the aquatic environment — Chronic, Cat. 1, H410 Contact with acids liberates very toxic gas, EUH032

For the wording of the listed risk phrases, please refer to section 16.

Section 4. FIRST-AID MEASURES

4.1 Description of first-aid measures

General information: Immediately remove contaminated clothing. Human blood samples and used pipette tips, test stripes and incubation trays can be infectious materials.

Inhalation exposure: This exposure is not possible.

Skin exposure: Wash with plenty of soap and water.

Eye exposure: Remove contact lenses. Flush with plenty of water for at least 10 - 15 minutes with open eyelids. If necessary, contact an ophthalmologist.

Oral exposure: Immediately wash out mouth with water. Drink a large glass (200 – 300 ml) of water in small sips (dilution effect). Do not induce vomiting. No neutralization efforts. If necessary, contact a doctor.

4.2 Most Important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication for any immediate medical attention and special treatment needed

Human blood samples, used pipette tips, test stripes and incubation trays can be infectious.

Section 5. FIREFIGHTING MEASURES

The solid components of the FastCheckPOC®20 are flammable (Fire Class A). The liquids components are not combustible.

As the FastCheckPOC®20 is used in laboratories, other flammable or explosive substances or mixtures, such as disinfectants, are in the surrounding area. The extinguishing agent must be adapted to operating conditions.

5.1 Suitable extinguishing media

Water, foam, carbon dioxide, powder, dry sands.

5.2 Unsuitable extinguishing media

None.

5.3 Special hazards arising from the product

In case of fire, hazardous fumes may arise (e.g. carbon monoxide, carbon dioxide).

5.4 Advice for firefighters

Prevent contaminated fire extinguishing water to seep into surface or ground-water and soil. Avoid skin contact by wearing appropriate protective clothing and keeping safety distance.

Section 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid skin contact by wearing appropriate protective clothing and by keeping a safety distance.
Advice for relief units: Use protective equipment in accordance with Section 8.

6.2 Environmental precautions

Prevent liquid reagents and contaminated water from entering waters, drains or soil.

6.3 Methods and materials for retaining and cleaning up

Spillages can be removed with towels since there are only small amounts of liquid. Collect for disposal in appropriate containers, according to local regulations.

6.4 Reference to other sections

Observe protection measures described in sections 7, 8 and 13.

Section 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Before starting, allow all solutions, the test stripes and the patient's sample to obtain room temperature (18 – 30 °C / 64 – 86 °F). Always have at hand: timer, beaker or comparable container for liquid waste and tap water.

Please comply with the following safety rules:

- Follow all common safety rules while handling components of the test.
- Avoid eye, oral and skin contact with all solutions.
- Human blood samples can be infectious. Wear disposable gloves and disinfect the working area after finishing the test.
- Developed FastCheckPOC® 20 devices can be infectious and have to be disposed (together with reagents, lancets, syringes and blood capillaries) in accordance with the local statutory rules and regulations that apply to medical/biological waste.
- Do not mix test components of different lots.
- Do not mix "the same" chemicals of different manufacturers.
- Do not use reagents that have passed their expiration date.
- In case of damage to the packaging please inspect the protecting bag of the cartridge carefully for damage and make sure that the cartridge and the membrane are intact (not wet etc.). Make sure that the bottles that contain the reagents are not damaged or open. In case of doubt, do not use the test kit thereby avoiding incorrect results or a wrong diagnosis.
- Use the FastCheckPOC® 20 test kit and its components only in accordance with the intended use.

7.2 Conditions for safe storage, including any incompatibilities

Store the FastCheckPOC®20 in a dark and cool place at 2 – 8 °C / 36 – 46 °F.

The expiration date is printed on labels placed on the test packaging box. The expiration date of the kit is valid for all kit components, even if the expiration of single components is different! After expiration, all test components have to be discarded.

Prohibitions on mixed storage:	Not applicable.
Incompatibilities:	Strong oxidants, higher temperature and moisture.
Other:	The colour reagent reacts colour intensively under the influence of light.

7.3 Specific end use(s)

For in vitro diagnostic use. Further information, see section 1.

Section 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

None.

8.2 Exposure controls

Not applicable.

Appropriate engineering controls: None.

Individual protection measures, such as personal protective equipment

Eye/face:	Wearing of safety glasses is recommended.
Skin:	Wear protective gloves which are suitable for daily laboratory use e.g. made of nitrile.
Respiratory:	Not mandatory.
Other:	No smoking, drinking and eating while working. After work and before breaks, wash hands thoroughly.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Component	Physical state, material
package leaflet	solid, paper
evaluation sheet	solid, paper
test cassette top bottom covers waste material	solid, Makrolon PC 2858 transparent Makrolon PC 2858 + MB white polycarbonate cellulose
membrane strips	solid, nitrocellulose
clip-bag	solid, polypropylene
safety lancet, sterile: needle/blade housing button needle support drive spring retraction spring needle carrier/safety tab	solid, AISI 302 or 304 stainless steel polypropylene polypropylene polypropylene/polyethylene zinc coated carbon steel wire zinc coated carbon steel wire polystyrene
blood sampling capillary capillary pestle filter	solid, without self-sealing Additives, with Lithium Heparin Cellidor Polyethylene hydrophobic Polyethylene
syringe: cylinder plunger	solid, polypropylene, transparent polyethylene, green
disinfection swab	non-woven cellulose with Isopropyl alcohol
band-aid	polyethylene foil, cellulose
cellulose swab	cellulose
sample dilutor	Non hazardous, aqueous solution.
washing solution	Non hazardous, aqueous solution.
colour reagent	Non hazardous, aqueous solution.
antibody solution 1	Non hazardous, aqueous solution with active biological component .
antibody solution 2	Non hazardous, aqueous solution with active biological component.
stop buffer	Non hazardous, aqueous solution.

Parameter	Sample dilutor DILUT	Washing solution WASH	Color reagent COLR	Antibody solution 1 Ab1	Antibody solution 2 Ab2	Stop buffer STOP	Isopropyl alcohol (disinfection swab)
Appearance	clear, colourless liquid	clear, slightly yellowish liquid	yellowish clear liquid	clear, colourless liquid	clear, colourless liquid	clear, slightly yellowish liquid	colourless liquid
Odour	no information available	no information available	no information available	no information available	no information available	no information available	alcohol-like
Odour threshold	no information available	no information available	no information available	no information available	no information available	no information available	no information available
pH (20 °C / 68 °F)	no information available	no information available	9,5 – 10,5	no information available	no information available	no information available	no information available
melting point / freezing (°C)	about 0°C	about 0°C	about 0°C	about 0°C	about 0°C	about 0°C	-88 °C
Initial boiling point and boiling range	about 100°C	about. 100°C	about 100°C	about 100°C	about 100°C	about 100°C	82 °C
Flash point	no information available	no information available	no information available	no information available	no information available	no information available	12 °C
Evaporation rate	no information available	no information available	no information available	no information available	no information available	no information available	no information available

Parameter	Sample dilutor DILUT	Washing solution WASH	Color reagent COLR	Antibody solution 1 Ab1	Antibody solution 2 Ab2	Stop buffer STOP	Isopropyl alcohol (disinfection swab)
Flammability (solid, gas)	not self-igniting	not self-igniting	not self-igniting	not self-igniting	not self-igniting	not self-igniting	highly flammable
Upper flammability or explosive limits	not self-igniting or explosive	not self-igniting or explosive	not self-igniting or explosive	not self-igniting or explosive	not self-igniting or explosive	not self-igniting or explosive	13,4 Vol.-% 335 g/m³
Lower flammability or explosive limits	not self-igniting or explosive	not self-igniting or explosive	not self-igniting or explosive	not self-igniting or explosive	not self-igniting or explosive	not self-igniting or explosive	2 Vol.-% 50 g/m³
Vapour pressure	no information available	no information available	no information available	no information available	no information available	no information available	42,6 hPa (20 °C)
Vapour density	no information available	no information available	no information available	no information available	no information available	no information available	2,07 g/cm³
Relative density (20 °C / 68 °F)	no information available	1 g/cm³	1,102 g/cm³	no information available	no information available	1,006 g/cm³	0,78 g/cm³
Solubility in water (20 °C / 68 °F)	completely soluble	completely soluble	completely soluble	completely soluble	completely soluble	completely soluble	completely soluble
Partition coefficient: n-octanol/ water	no information available	no information available	no information available	no information available	no information available	no information available	log Kow: 0,05
Auto-ignition temperature	not self-igniting	not self-igniting	not self-igniting	not self-igniting	not self-igniting	not self-igniting	425 °C
Decomposition temperature	no information available	no information available	no information available	no information available	no information available	no information available	no information available
Viscosity	no information available	no information available	no information available	no information available	no information available	no information available	no information available
Explosive properties	not explosive	not explosive	not explosive	not explosive	not explosive	not explosive	Vapors form explosive mixtures with air
Oxidising properties	no information available	no information available	no information available	no information available	no information available	no information available	no information available

9.2 Other information

None.

Section 10. ABILITY AND REACTIVITY

10.1 Reactivity

The colour reagent reacts colour intensively under the influence of light.

10.2 Chemical stability

The FastCheckPOC®20 and its liquid reagents are chemically stable for the use and storage if the conditions are as specified in section 7.

10.3 Possibility of hazardous reactions

None.

10.4 Conditions to avoid

Avoid high temperature and moisture. For colour reagent, avoid exposure to light.

10.5 Incompatible materials

Avoid strong oxidants.

10.6 Hazardous decomposition products

None.

Section 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

There are no toxicological findings for the FastCheckPOC®20.

Acute toxicity: No data available.
Skin corrosion/irritation: No data available.
Serious eye damage/irritation: No data available.
Respiratory or skin sensitisation: No data available.
Germ cell mutagenicity: No data available.
Carcinogenicity: No data available.
Reproductive toxicity: No data available.
STOT-single exposure: No data available.
STOT-repeated exposure: No data available.
Aspiration hazard: No data available.

Information on likely routes of exposure: No data available.
Symptoms related to the physical, chemical and toxicological characteristics: No data available.
Delayed and immediate effects as well as chronic effects from short and long-term exposure: No data available.
Interactive effects: No data available.
Other information: No data available.

Section 12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bio accumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

The product, incl. all ingredients of the liquid reagents, does not meet the criteria for classification as PBT (persistent, bio accumulative and toxic at the same time) or vPvB (very persistent and very high bioaccumulation).

12.6 Other adverse effects

No data available.

Section 13. DISPOSAL CONSIDERATION

13.1 Waste treatment methods

Disposal of residual quantities and waste of the product

Developed FastCheckPOC® 20 test stripes and human blood samples can be infectious and (together with pipette tips, incubation trays and sample vials) have to be disposed of in accordance with the local statutory rules and regulations that apply to medical/biological waste.

Disposal of contaminated packaging

Contaminated packaging should be treated like residues and waste of the product.

Disposal of emtied packaging

Uncontaminated and cleaned packaging can be recycled.

Section 14. TRANSPORT INFORMATION

RID / ADR / IMDG-Code: This product is considered to be non-hazardous with regard to transport.
ICAO-IATA: This product is considered to be non-hazardous with regard to transport.

14.1 UN number

Not Applicable. This product is considered to be non-hazardous with regard to transport.

14.2 UN proper shipping name

Not Applicable. This product is considered to be non-hazardous with regard to transport.

14.3 Transport hazard class(es)

Not Applicable. This product is considered to be non-hazardous with regard to transport.

14.4 Packing group

Packing group III – Low risk substances.

14.5 Environmental hazards

This product is considered to be non-hazardous with regard to transport.

14.6 Special precautions for user

This product is considered to be non-hazardous to the user. Personal protective equipment is recommended, see chapter 8.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not Applicable. This product is considered to be non-hazardous with regard to transport.

Section 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

CLP (EG) No. 1272/2008
REACH (EU) No. 2015/830.
Regulation (EU) 2015/830 for amending REACH

15.2 Chemical safety assessment:

For this product, including all liquid components, no safety assessment was made.

Section 16. ADDITIONAL INFORMATION

16.1 Changes since the last version

Section 1: Product numbers added; Detailed description of uses advised against
Section 3: Reagents: shorthand symbol added (DILUT, WASH, Ab1, Ab2, COLR, STOP); Fig. 1 removed; composition of the mixtures updated; classification according to Directive 67/548/EEC removed (only Regulation (EC) No. 1272/2008 applies); isopropyl alcohol added
Section 9: Characteristics expanded in accordance to (EU) 2015/830; isopropyl alcohol added
Sections 10, 11, 12, 14: Sub-sections according to 2015/830 added and updated
Section 16: Updating of the hazard statements (classifications according to Directive 67/548/EEC removed, only Regulation (EC) No. 1272/2008 applies)

16.2 Literature and data sources

Regulations:
CLP (EG) No. 1272/2008
REACH (EU) No. 2015/830
Regulation (EU) 2015/830 for amending REACH

Internet:
http://www.baua.de
http://gestis.itrust.de
http://echa.europa.eu/en/candidate-list-table

16.3 Hazards referenced in section 3

There are no hazardous ingredients in an amount which requires the identification and marking according to European Community guidelines.

Classification according to (EC) No. 1272/2008

Corrosive against metals, Cat. 1, H290: May be corrosive to metals.
Acute Toxicity, Cat. 1 + 2, swallow, H300: Fatal if swallowed.
Acute Toxicity, Cat. 3 + 4, H302: Harmful if swallowed.
Acute Toxicity, Cat. 2, skin, H310: Fatal in contact with skin.
Skin corrosion, Cat. 1B, H314: Causes severe skin burns and eye damage.

Skin irritation, Cat. 2, H315: Causes skin irritation.
Skin sensitisation, Cat. 1, H317: May cause an allergic skin reaction.
Eye irritation, Cat. 2, H319: Causes serious eye irritation.
Acute Toxicity, Cat. 1, inhalation, H330: Fatal if inhaled.
Acute Toxicity, Cat. 4, H331: Toxic if inhaled.
STOT - Specific target organ toxicity (single exposure), Cat. 3, H335: May cause respiratory irritation.
STOT - Specific target organ toxicity (single exposure), Cat. 3, H336: May cause drowsiness or dizziness.
STOT - Specific target organ toxicity (repeated exposure), Cat. 2 (brain), H373: May cause damage to organs through prolonged or repeated exposure (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).
Hazardous to the aquatic environment — Acute, Cat. 1, H400: Very toxic to aquatic life.
Hazardous to the aquatic environment — Chronic, Cat. 1, H410: Very toxic to aquatic life with long lasting effects.
EUH032: Contact with acids liberates very toxic gas

16.4 Please note

Read the leaflet before using the test kit. The General Terms and Conditions of Business apply.
The information in this product data sheet is based on our present state of knowledge but does not represent a guarantee of product properties and establishes no contractual legal rights.