Section 1: COMPANY AND PRODUCT INFORMATION

1.1 Product Name:	PECheck™ PAPP-A2 ELISA
1.2 Product Code:	AL-1015-r
1.3 Product Category:	**GMDN: 65862 / EDMA N.A**
1.4 Manufacturer:	**Manufacturer:** Ansh Labs 445 Medical Center Blvd Webster, TX 77598 Ph: (281) 404-0260 techsupport@anshlabs.com
1.5 Emergency telephone number:	Emergency telephone (24 h): 911 Poison Control: 1-800-222-1222 In the event of a medical emergency, please contact your local medical authority.
1.6 Relevant identified uses of the substance/mixture:	For the quantitative measurement of PAPP-A2 in human maternal serum and other biological fluids. For **Research Use Only**.
uses advised against:	Not for use in diagnostic procedures or therapeutic applications. Intended for laboratory professionals experienced in immunoassay techniques

1.7 Kit content (name and label reference):

Component (Part No.)	Description	Hazard Information
CAL-1015A	PECheck PAPP-A2 Calibrator A / Sample Diluent - in a protein-based buffer with ≤0.09% Sodium Azide.	EUH208; H400-H410
CAL-1015 (B-F)	PECheck PAPP-A2 Calibrators (B-F) - in a protein-based buffer with ≤0.09% Sodium Azide.	EUH208; H400-H410
CTR-1015 (I-II)	PECheck PAPP-A2 Controls (I-II) - in a protein-based buffer with ≤0.09% Sodium Azide.	EUH208; H400-H410
PLT-109	PAPP-A2 Antibody Coated Microtitration Strips	Article – not hazardous
ASB-109	PAPP-A2 Assay Buffer - in a protein-based buffer with ≤0.5% ProClin™ 300/Pro-Clean™ 400.	EUH208; H400-H410
BCR-1015	PAPP-A2 Conjugate Ready-To-Use (RTU) - in a protein-based buffer with ≤0.5% ProClin™ 300/Pro-Clean™ 400.	EUH208; H400-H410
SAR-1015	PAPP-A2 Streptavidin-Enzyme Conjugate Ready-To-Use (RTU) - in a protein-based buffer with ≤0.5% ProClin™ 300/Pro-Clean™ 400.	EUH208; H400-H410
TMB-100	Substrate Solution – tetramethylbenzidine (TMB) in buffer.	Eye Irrit. 2 (H319)

STP-100	Stopping Solution - 0.2M Sulfuric Acid	Skin Corr. 1A (H314); Eye Dam. 1 (H318)
WSH-100	Wash Buffer Concentrate (25x) – Phosphate Buffered Saline Solution with a non-ionic detergent.	EUH208

Section 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

According to Regulation (EC) No 1272/2008 (CLP) as amended:

This mixture is not classified as hazardous under the criteria of Regulation (EC) No 1272/2008 (CLP).
It contains trace concentrations of preservatives (isothiazolinones ≤ 0.25%, sodium azide ≤ 0.1%) and dilute sulfuric acid (< 2%), all present below the concentration limits for classification.
The mixture does not meet the criteria for physical, health, or environmental hazard classification under CLP.

Intended use: For laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.

2.2 Label elements

Sulfuric acid:



DANGER H314 Causes severe skin burns and eye damage.
P280 Wear protective gloves, protective clothing and eye/ face protection.
P301+P330+P331 If swallowed: rinse mouth.
P303+P361+P353 If on skin: (or hair): Rinse skin with water.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Continue rinsing.
P310 Immediately seek physician assistance.

Pro-clean 400/Proclin 300:



R23/24/25: Hārmful if inhaled,

in contact with skin and if swallowed

H317 May cause an allergic skin reaction
P261 Avoid breathing vapors
P272 Contaminated work clothing should not be allowed out of the workplace

	P280 Wear protective gloves, protective clothing and eye/face protection P302+P352 If on skin: Wash with plenty of soap and water P333+P313 If skin irritation or rash occurs, seek medical assistance. **Sodium Azide:**  Danger: H300 + H310 + H330 Fatal if swallowed, in contact with skin or if inhaled. H373 May cause damage to organs (Brain) through prolonged or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting effects. P301 + P310 + P330 If swallowed: Immediately call a POISON CENTER/ doctor. Rinse mouth. P302 + P352 + P310 If on skin: Wash with plenty of water. Immediately call a POISON CENTER/ doctor. P280 Wear protective gloves, protective clothing and eye/face protection. P272 Contaminated work clothing should not be allowed out of the workplace.
2.3 Hazards not otherwise classified (HNOC) or not covered by GHS:	• **PBT / vPvB assessment:** The mixture does not contain any substances identified as PBT or vPvB according to Annex XIII of REACH. • **Endocrine-disrupting properties:** None of the components are identified as having endocrine-disrupting properties under REACH or CLP. • **Biological origin:** Some kit components may contain materials of human origin (e.g., serum-based buffers). These are tested and found non-reactive for known pathogens but should be handled using Biosafety Level 2 precautions per CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories,* 5th Edition. The product also contains proteins of bovine or equine origin sourced from OIE-classified negligible BSE-risk herds in accordance with Reg. (EC) No 999/2001 and Commission Decision 2007/453/EC. **Other hazards:** Contains trace concentrations of isothiazolinones (< 0.25 %) and sodium azide (< 0.1 %) which are below classification thresholds but may cause sensitization in susceptible individuals. Under normal conditions of use, the mixture does not present any additional physical, health, or environmental hazards.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Stopping Solution		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**US OSHA**	**WHMIS**
Sulfuric Acid **CAS #** 7664-93-9 **EINECS #** 231-639-5 **Index #** 016-020-00-8	<2	C;R35	Eye Dam. 1 Skin Corr. 1A H314; H318	Water-Reactive Carcinogen Corrosive Highly Toxic	D1A; E

3.2 Mixtures

This kit comprises buffered aqueous solutions and protein-based reagents containing the components listed below. Hazardous constituents are present at concentrations below classification thresholds under Regulation (EC) No 1272/2008 (CLP).

PAPP-A2 Assay Buffer, PAPP-A2 Conjugate RTU, PAPP-A2 Streptavidin-Enzyme Conjugate RTU		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**US OSHA**	**WHMIS**
Pro-clean 400[2,8]**/ProClin™ 300**[2,8] reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one	< 0.5	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311;	Corrosive Sensitizer Toxic	D1B; D2B; E
PECheck PAPP-A2 Calibrator A/Sample Diluent, PECheck PAPP-A2 Calibrators (B-F), PECheck PAPP-A2 Controls (I-II)		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**US OSHA**	**WHMIS**
Sodium Azide[2,8] **CAS #** 26628-22-8 **EINECS #** 247-852-1 **Index #** 011-004-00-7	< 0.1	T+; R28-32 N; R50/53	T+; R28-32 N; R50/53 Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Highly Toxic Irritant	D1A

Notes:

- The preservative originally referenced as “Pro-Clean 400” in product literature corresponds to ProClin™ 300 (reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (3:1)).
- *The specific chemical identity and/or exact concentration has been withheld as a trade secret in accordance with 29 CFR 1910.1200 (i) (U.S.) and protected under Article 24 of Regulation (EC) No 1272/2008 (EU CLP). All relevant hazard and precautionary information is provided to ensure safe handling.

Section 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice:	No special measures required. Consult a physician in case of complaints.

If inhaled:	If product is inhaled, move exposed individual to fresh air.
In case of skin contact:	In case of skin contact, flush with water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.
In case of eye contact:	If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.
If swallowed:	If ingested, wash mouth out with water. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed:
To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed
No data available.

Section 5: FIREFIGHTING MEASURES

5.1 Flammable Properties:
Nonflammable solution.

5.2 Extinguishing media:
Chemical or water fire extinguisher.

5.3 Special hazards arising from the substance or mixture:
No special hazards determined.

5.4 Advise for Firefighters
Wear self-contained breathing apparatus for firefighting, if necessary.

5.5 NFPA Rating

Health: 2
Flammability: 0
Reactivity: 1

Section 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:
Use appropriate personal protective equipment (Wear rubber gloves, safety goggles, impermeable shoe covers and long laboratory coat).

6.2 Spill and Leak Procedures:
Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.3 Environmental precautions:
Contain the spill to the smallest area possible. Do not let product enter drains. Discharge into the environment must be avoided.

6.4 Methods and material for containment and cleaning up:
Absorb with inert absorbent material and dispose of a waste (see section 13).

6.5 Reference to other sections:
For disposal see section 13.

Section 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:
Wear suitable personal protective equipment. Take care not to splash spill or splatter reagents. Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette samples or reagents by mouth.

7.2 Recommended Storage and Conditions:
Keep away from incompatible material (see Section 10).
To maintain efficacy, store according to the instructions in the product labelling

7.3 Specific end use(s):
This product is intended for laboratory use by professional users only.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters:

Substance	EU IOELV / OEL (TWA 8 h)	OSHA PEL (8 h TWA)	ACGIH TLV	NIOSH REL	DFG MAK	Notes
Sulfuric acid (aerosol, thoracic fraction)	0.05 mg/m³ (TWA, Directive 2000/39/EC)	1 mg/m³	0.2 mg/m³ (thoracic fraction)	1 mg/m³	0.1 mg/m³	Irritant threshold limit

Sodium azide (as NaN_3)	None established	None established	0.1 mg/m³ ceiling	0.1 mg/m³ ceiling	None	Applies only for aerosols/powder
Reaction mass of CMIT/MIT (3:1)	None established	None established	None	None	None	Trace preservative (<0.25%) – EUH208 applies

8.2 Exposure controls

- Engineering controls: Use only in a well-ventilated laboratory. Handle open reagents under local exhaust ventilation or a chemical fume hood to avoid aerosol generation.
- Eye/face protection: Safety glasses with side-shields or chemical goggles conforming to EN 166 / ANSI Z87.1.
- Hand protection: Disposable nitrile, neoprene, latex or rubber gloves (EN 374). Replace immediately if contaminated or torn.
- Body protection: Laboratory coat or equivalent protective garment.
- Respiratory protection: Not normally required under intended use. If airborne concentrations may exceed limits, use an approved respirator (NIOSH N95 / EU P2) after evaluation by a qualified safety professional.
- Environmental controls: Avoid release to drains or waterways. Flush waste solutions with excess water to prevent metal-azide accumulation in plumbing.
- Hygiene measures: Follow good laboratory practice. Do not eat, drink, or smoke while handling reagents. Wash hands thoroughly after use.

8.3 Personal protective equipment:

- This mixture is supplied as a small-volume in vitro diagnostic reagent kit for professional laboratory use only.
- REACH exposure scenarios: Not required; quantities are below registration thresholds.
- Regulatory alignment: Information in this SDS meets or exceeds requirements of EU REACH / CLP (2020/878), UK REACH, U.S. OSHA HazCom 2012 (29 CFR 1910.1200), ACGIH TLVs, NIOSH RELs, DFG MAKs, and GHS-aligned systems in Switzerland, Turkey, GCC, and China.
- Typical laboratory precautions: Avoid splashes and aerosols; open vials slowly; maintain secondary containment for liquids. Engineering and PPE measures above are adequate for all listed jurisdictions.
- Intended end use: Diagnostic or research use testing only; not for consumer or industrial manufacturing use. Product is exempt from OSHA workplace labeling when supplied in sealed diagnostic kits.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Component	a) **Appearance**	b) **Odor**	c) **pH**
PECheck PAPP-A2 Calibrator A / Sample Diluent	Liquid, clear	Odorless	7.4
PECheck PAPP-A2 Calibrators (B-F)	Lyophilized powder	Odorless	7.4
PECheck PAPP-A2 Controls (I-II)	Lyophilized powder	Odorless	7.4
PAPP-A2 Ab Plate	Plastic, clear plate	Odorless	N/A
PAPP-A2 Conjugate Ready-to-Use	Liquid, colorless	Odorless	7.8

PAPP-A2 Streptavidin-Enzyme Conjugate Ready-to-Use	Liquid, yellow	Odorless	6.25	
Stop Solution	Liquid, colorless	Odorless	1.2	
TMB solution	Liquid, colorless	Odorless	4.0	
Wash Concentrate A	Liquid, colorless	Odorless	7.2	

9.2 Other information:

No additional physicochemical information relevant to safe use.

Section 10: STABILITY AND REACTIVITY

10.1 Reactivity: Stable under normal laboratory conditions.
10.2 Chemical stability: Stable at 2–8 °C within stated shelf life.
10.3 Possibility of hazardous reactions: None known under normal use; avoid mixing with incompatible materials.
10.4 Conditions to avoid: Freezing, excessive heat, drying out; aerosol generation.
10.5 Incompatible materials: Strong acids and bases; strong oxidizing agents; reactive metals (may form metal azides with azide-containing residues).
10.6 Hazardous decomposition products: Thermal decomposition may release oxides of sulfur, nitrogen, and carbon.

Section 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

- Acute toxicity (oral/dermal/inhalation): Not classified for the mixture. Sodium azide and isothiazolinones are present below classification thresholds.
- Skin corrosion/irritation: Not classified; prolonged or repeated contact may cause transient irritation.
- Serious eye damage/irritation: Not classified; splashes may cause transient irritation. The stopping solution is corrosive at component level but below classification threshold at mixture level.
- Respiratory or skin sensitization: Contains isothiazolinones (CMIT/MIT) which may cause skin sensitization in susceptible individuals (EUH208).
- Germ cell mutagenicity: No data indicating mutagenic effects for the mixture.
- Carcinogenicity: No components are classified as carcinogenic by IARC, NTP, EU CLP.
- Reproductive toxicity: No data indicating reproductive effects for the mixture.
- STOT – single exposure: Not classified.
- STOT – repeated exposure: Not classified.
- Aspiration hazard: Not applicable (aqueous mixtures of low viscosity and low hydrocarbon content).

11.2 Information on other hazards

No evidence of endocrine disrupting properties is available for this mixture. The product is intended for professional laboratory use; exposure is expected to be minimal under recommended handling conditions.

Section 12: ECOLOGICAL INFORMATION

12.1 Toxicity: This mixture is not classified as hazardous to the environment. Contains very small quantities of sodium azide and isothiazolinones which are toxic to aquatic organisms at higher

concentrations. Due to the low volume and dilution used in diagnostic testing, environmental exposure is minimal.

12.2 Persistence and degradability: Components are primarily biodegradable. Small amounts of preservatives may persist in aquatic environments.

12.3 Bioaccumulative potential: No data available for the mixture. Sodium azide has low bioaccumulation potential.

12.4 Mobility in soil: Expected to be mobile in soil due to water solubility of components.

12.5 Results of PBT and vPvB assessment: The mixture does not contain any substances identified as PBT or vPvB according to Annex XIII of REACH.

12.6 Endocrine disrupting properties: None known or expected based on available data.

12.7 Other adverse effects: Avoid uncontrolled release to the environment. Flush small quantities with excess water.

Section 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:
Dispose of contents and containers in accordance with local, regional, national, and international regulations. Small quantities may be diluted with large volumes of water and discharged to drain after neutralization. Do not dispose of sodium azide solutions via metal plumbing due to potential formation of explosive metal azides. Contaminated packaging: Rinse thoroughly before recycling or disposal as laboratory waste. Follow all applicable regulations under EU Directive 2008/98/EC, U.S. EPA (40 CFR Part 261), and other local environmental authorities.

Section 14: TRANSPORT INFORMATION

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG, because it is in a very small quantity, the product benefits from a total exemption from the ADR regulation.

14.1 UN Number:
Not applicable (mixture not classified as dangerous for transport).

14.2 UN proper shipping name:
Not applicable.

14.3 Transport hazard class(es):
Not regulated as hazardous under ADR/RID/IMDG/IATA/ICAO or U.S. DOT.

14.4 Packing group:
Not applicable.
.

14.5 Environmental hazards:
Not classified as environmentally hazardous for transport.

14.6 Special precautions for user:
Handle as laboratory reagent; avoid leaks or spills. Ensure containers remain tightly closed during transport.
.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
This product is not intended for bulk transport under the terms of Annex II of MARPOL or the International Bulk Chemical (IBC) Code.
The mixture is supplied exclusively in sealed primary containers as part of small-volume in vitro diagnostic reagent kits, not as bulk liquid cargo.
Therefore, no ship type assignment or pollution category applies.

Section 15: REGULATORY INFORMATION

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

European Union / EEA
- Prepared in accordance with Regulation (EC) No 1907/2006 (REACH) as amended by Regulation (EU) 2020/878, and classified under Regulation (EC) No 1272/2008 (CLP).
- Waste management per Directive 2008/98/EC.
- Animal-derived components comply with Regulation (EC) No 999/2001 and Commission Decision 2007/453/EC.
- This product is for research use only (RUO) and is not subject to EU IVDR (2017/746) or CE marking requirements.

United Kingdom
- Complies with UK REACH and GB CLP Regulations (The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019).

United States
- Complies with the OSHA Hazard Communication Standard (29 CFR 1910.1200) (HazCom 2012).
- Components are listed or exempt on the U.S. TSCA Inventory.
- Waste disposal is subject to EPA Resource Conservation and Recovery Act (40 CFR Parts 260–273).
- Product contains no infectious or biohazardous material and is not regulated as an infectious substance under the U.S. DOT Hazardous Materials Regulations (49 CFR 173).

Canada
- Complies with Hazardous Products Regulations (SOR/2015-17) aligned with WHMIS 2015 (GHS Rev. 5).
- Components are listed or exempt under the Domestic Substances List (DSL) or Non-Domestic Substances List (NDSL).

Other jurisdictions
- Switzerland – ChemO Art. 54 (accepts EU SDS format)

- Turkey – KKDIK Reg. 30105 and SEA Reg. 28848 (REACH/CLP equivalent)
- Gulf Cooperation Council (GCC) / Saudi Arabia – Implementing GHS Rev. 6; English SDS accepted
- China (PRC) – GB/T 16483-2008 and GB 30000 series
- Japan – ISHL and GHS (JIS Z 7253:2019)
- Australia – WHS Regulations and SDS Code of Practice 2011; listed or exempt on AICS
- Korea – K-REACH and KECI inventory compliant

Label Elements (EU CLP)

- No hazard pictogram or signal word required
- EUH208 – Contains CMIT/MIT (3:1) and sodium azide. May produce an allergic reaction.

Authorizations and Restrictions

- None of the substances in this mixture are subject to REACH Annex XIV (authorization) or Annex XVII (restriction).
- Substances of Very High Concern (SVHC)
- No SVHC present ≥ 0.1 % (w/w).

Chemical Inventories

All intentionally added components are listed or exempt on the following national or regional inventories: EU REACH, UK REACH, US TSCA, Canada DSL/NDSL, Australia AICS, China IECSC, Japan ENCS, Korea KECI, Philippines PICCS, and New Zealand NZIoC.

Bovine/Equine Material Compliance

All animal-derived materials originate from OIE-classified negligible BSE-risk herds and comply with Regulation (EC) No 999/2001.

15.2 Chemical safety assessment

A chemical safety assessment has not been performed for this mixture. The product is supplied in small volumes for professional in vitro diagnostic use only, and potential exposure is minimal under normal laboratory conditions.

Section 16: OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

16.1 Abbreviations and acronyms

ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road
ACGIH – American Conference of Governmental Industrial Hygienists
BSE – Bovine Spongiform Encephalopathy
CAS – Chemical Abstracts Service
CLP – Classification, Labelling and Packaging Regulation
DNEL – Derived No-Effect Level
DOT – U.S. Department of Transportation
GHS – Globally Harmonised System
IATA – International Air Transport Association
IMDG – International Maritime Dangerous Goods Code
NIOSH – U.S. National Institute for Occupational Safety and Health
OEL – Occupational Exposure Limit
OSHA – U.S. Occupational Safety and Health Administration

PBT – Persistent, Bioaccumulative and Toxic
PNEC – Predicted No Effect Concentration
REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC – Substance of Very High Concern
TSE – Transmissible Spongiform Encephalopathy
vPvB – Very Persistent and Very Bioaccumulative

16.2 Training advice
Product intended for professional use only. Laboratory personnel should receive training in safe handling of diagnostic reagents and chemical hygiene.

16.3 Further information
The information herein is believed to be correct at the time of publication and is provided in good faith. It describes safety requirements but does not constitute a product specification or guarantee.

Ansh Labs, 445 Medical Center Blvd, Webster, TX 77598 USA
Tel: +1 (281) 404-0260 Email: techsupport@anshlabs.com