Section 1: COMPANY AND PRODUCT INFORMATION

1.1 Product Name: picoAMH ELISA

1.2 Product Code: AL-124, AL-124-i

1.3 Product Category: GMDN N.A / EDMA N.A

1.4 Manufacturer: Ansh Labs

Manufacturer:
Ansh Labs
445 Medical Center Blvd
Webster, TX 77598
Ph: (281) 404-0260

EC Representative:
Dr C.R.Bhaduri
RD-RatioDiagnostics GmbH
Westerbachstrabe 47
60489 Frankfurt/Main
Germany
Ph: +49 7807-4942

technsupport@anshlabs.com

1.5 Emergency telephone number: In the event of a medical emergency, please dial 911.

1.6 Relevant identified uses of the substance/mixture: Research Use Only. For in vitro professional laboratory use.

uses advised against: For the quantitative measurement of picoAMH in human serum and other biological fluids.

1.7 Kit content (name and label reference):

<table>
<thead>
<tr>
<th>Component</th>
<th>Part Number</th>
<th>Quantity</th>
<th>Main Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>picoAMH Calibrator A/ Sample Diluent (0ng/mL)</td>
<td>CAL-124A</td>
<td>10 mL</td>
<td>Serum based with Pro-clean 400 (0.05%) and Sodium Azide (0.09%)</td>
</tr>
<tr>
<td>picoAMH Calibrator B (Lyophilized)</td>
<td>CAL-124B</td>
<td>1 vial</td>
<td>Serum based with Pro-clean 400 (0.05%) and Sodium Azide (0.09%)</td>
</tr>
<tr>
<td>picoAMH Calibrator C (Lyophilized)</td>
<td>CAL-124C</td>
<td>1 vial</td>
<td>Serum based with Pro-clean 400 (0.05%) and Sodium Azide (0.09%)</td>
</tr>
<tr>
<td>picoAMH Calibrator D (Lyophilized)</td>
<td>CAL-124D</td>
<td>1 vial</td>
<td>Serum based with Pro-clean 400 (0.05%) and Sodium Azide (0.09%)</td>
</tr>
<tr>
<td>picoAMH Calibrator E (Lyophilized)</td>
<td>CAL-124E</td>
<td>1 vial</td>
<td>Serum based with Pro-clean 400 (0.05%) and Sodium Azide (0.09%)</td>
</tr>
<tr>
<td>picoAMH Calibrator F (Lyophilized)</td>
<td>CAL-124F</td>
<td>1 vial</td>
<td>Serum based with Pro-clean 400 (0.05%) and Sodium Azide (0.09%)</td>
</tr>
<tr>
<td>picoAMH Control I (Lyophilized)</td>
<td>CTR-124-I</td>
<td>1 vial</td>
<td>Serum based with Pro-clean 400 (0.05%) and Sodium Azide (0.09%)</td>
</tr>
<tr>
<td>picoAMH Control II (Lyophilized)</td>
<td>CTR-124-II</td>
<td>1 vial</td>
<td>Serum based with Pro-clean 400 (0.05%) and Sodium Azide (0.09%)</td>
</tr>
<tr>
<td>Anti-AMH Antibody Coated Microtitration Strips</td>
<td>PLT-124</td>
<td>1 Each</td>
<td>Antibody Coated Polystyrene Plate</td>
</tr>
<tr>
<td>AMH/MIS Assay Buffer</td>
<td>ASB-205</td>
<td>12 mL</td>
<td>Protein based (-BSA) Buffer with Pro-Clean 400</td>
</tr>
<tr>
<td>picoAMH Biotin Conjugate Ready-to-Use (RTU)</td>
<td>BCR-124</td>
<td>12 mL</td>
<td>Protein based Buffer with Pro-Clean 400</td>
</tr>
<tr>
<td>picoAMH Streptavidin-Enzyme Conjugate Ready-to-Use (RTU)</td>
<td>SAR-124</td>
<td>12 mL</td>
<td>Protein based Buffer with Pro-Clean 400</td>
</tr>
<tr>
<td>Stopping Solution</td>
<td>STP-100</td>
<td>12 mL</td>
<td>0.2 M Sulfuric Acid</td>
</tr>
<tr>
<td>TMB Solution</td>
<td>TMB-100</td>
<td>12 mL</td>
<td>Buffer with trace amounts of DMSO and hydrogen peroxide</td>
</tr>
<tr>
<td>Wash Concentrate A</td>
<td>WSH-100</td>
<td>60 mL</td>
<td>Buffer with a nonionic detergent</td>
</tr>
<tr>
<td>Section 2 : HAZARDS IDENTIFICATION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2.1 Classification of the substance or mixture:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None of the material of this product may be classified as dangerous according to EC Directives 1999/45/EC, 67/548/EEC and 1272/2008/EC due to the low concentration of hazardous ingredients.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>2.2 Label elements</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stopping solution:</strong></td>
</tr>
<tr>
<td>DANGER H314 Causes severe skin burns and eye damage.</td>
</tr>
<tr>
<td>P280 Wear protective gloves, protective clothing and eye/face protection.</td>
</tr>
<tr>
<td>P301+P330+P331 If swallowed: rinse mouth.</td>
</tr>
<tr>
<td>P303+P361+P353 If on skin (or hair): Rinse skin with water.</td>
</tr>
<tr>
<td>P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Continue rinsing.</td>
</tr>
<tr>
<td>P310 Immediately seek physician assistance.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>2.3 Hazards not otherwise classified (HNOC) or not covered by GHS:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pro-clean 400:</strong></td>
</tr>
<tr>
<td>R23/24/25: Harmful if inhaled, in contact with skin and if swallowed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Not applicable.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Note: this product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.</td>
</tr>
</tbody>
</table>

| **The Calibrators and Controls are formulated with a buffer base, Protein Based Buffer and Human serum. The human serums are tested by a CE/FDA licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product.** |

| **Bovine products (BSA) have been derived from US origin and processed in USDA licensed facilities, and are free from known infections, however, it should be considered that no available test method can offer complete assurance of eliminating potential biohazardous risk. The antibodies are from monoclonal origin and are free from human or animal source.** |
Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

<table>
<thead>
<tr>
<th>Stopping Solution</th>
<th>Hazard Classification of Pure Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Name</td>
<td>% by wt.</td>
</tr>
<tr>
<td>Sulfuric Acid</td>
<td>&lt;2</td>
</tr>
</tbody>
</table>

| 3.2 Mixtures |

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.
9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of Pro-Clean 400

<table>
<thead>
<tr>
<th>Pro-Clean 400</th>
<th>Hazard Classification of Pure Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one <a href="">EC# 220-239-6</a></td>
<td></td>
</tr>
<tr>
<td>CAS # 55965-84-9</td>
<td>EINECS # Not available</td>
</tr>
<tr>
<td>≤ 0.5</td>
<td>T+;R23/24/25-34-43 N;R50/53</td>
</tr>
<tr>
<td>Corrosive</td>
<td>Sensitizer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>picoAMH Calibrators and Controls</th>
<th>Hazard Classification of Pure Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Azide</td>
<td></td>
</tr>
<tr>
<td>CAS # 26628-22-8</td>
<td>EINECS # 247-852-1</td>
</tr>
<tr>
<td>&lt; 0.1</td>
<td>T+;R28-32 N;R50/53</td>
</tr>
<tr>
<td>Highly Toxic</td>
<td>Iritant</td>
</tr>
</tbody>
</table>

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 occur, 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:
Component with exposure limits: it doesn't contain substances with exposure limit value.

8.2 Exposure controls
Handle in accordance with good industrial hygiene and safety practice.
Wash hands before breaks at the end of workday.
8.3 Personal protective equipment:

US OSHA: None established.

ACGIH: None established.

DFG MAK: None established.

NIOSH: None established.

Japan: None established.

Engineering Controls: Use in well-ventilated area.

Eye/face protection: Safety glasses or chemical goggles should be worn to prevent eye contact.

Skin protection: Lab coats, non-permeable rubber, neoprene, latex or nitrile disposable gloves.

Body protection: Lab coats.

Respiratory protection: Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

<table>
<thead>
<tr>
<th>Component</th>
<th>a) Appearance</th>
<th>b) Odor</th>
<th>c) pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>picoAMH Calibrator A</td>
<td>Liquid, clear</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>picoAMH Calibrators B-F</td>
<td>Lyophilized, white</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>picoAMH Controls</td>
<td>Lyophilized, white</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>Anti-AMH Ab Plate</td>
<td>plastic, clear plate</td>
<td>odorless</td>
<td>N/A</td>
</tr>
<tr>
<td>picoAMH Assay Buffer</td>
<td>Liquid, clear</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>picoAMH Biotin Conjugate Ready-to-Use</td>
<td>Liquid, clear</td>
<td>odorless</td>
<td>7.4</td>
</tr>
<tr>
<td>picoAMH Stretavidin-Enzyme Conjugate Ready-to-Use (RTU)</td>
<td>liquid, colorless</td>
<td>Odorless</td>
<td>6.2</td>
</tr>
<tr>
<td>Stop Solution</td>
<td>liquid, colorless</td>
<td>odorless</td>
<td>1.2</td>
</tr>
<tr>
<td>TMB solution</td>
<td>liquid, colorless</td>
<td>odorless</td>
<td>4.0</td>
</tr>
<tr>
<td>Wash Concentrate A</td>
<td>liquid, colorless</td>
<td>odorless</td>
<td>7.2</td>
</tr>
</tbody>
</table>

For all components:

d) odor threshold | no data available  
e) melting point / freezing point | no data available  
f) initial boiling point and boiling range | no data available  
g) flash point | no data available
h) evaporation rate  
   no data available

i) flammability (solid, gas)  
   no data available

j) upper/lower flammability or explosive limits  
   no data available

k) vapor pressure  
   no data available

l) vapor density  
   no data available

m) relative density  
   no data available

n) solubility(ies)  
   no data available

o) partition coefficient: n-octanol / water;  
   no data available

p) auto-ignition temperature  
   no data available

q) decomposition temperature  
   no data available

r) viscosity  
   no data available

s) explosive properties  
   no data available

t) oxidizing properties  
   no data available

9.2 Other information:  
   No other information available

Section 10: STABILITY AND REACTIVITY

10.1 Reactivity:  
   No data available.

10.2 Chemical stability:  
   No data available.

10.3 Possibility of hazardous reactions:  
   Concentrated Sodium Azide may react with copper and lead plumbing to form explosive metal azides. May react with acids to form explosive hydrazoic acid. If drain disposed, flush with large amounts of water to prevent azide build-up.

10.4 Conditions to avoid:  
   For the functional stability and reactivity of “TMB Substrate” avoid its exposure to direct sunlight, metals or oxidants and do not freeze the solution.

10.5 Incompatible materials:  
   Strong acids; strong bases; strong oxidizers.

10.6 Hazardous decomposition products:  
   No decomposition products posing significant hazards would be expected from this product.

Section 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:  
  a) acute toxicity  
     no data available

  b) skin corrosion/irritation  
     no data available

  c) serious eye damage / irritation  
     no data available
### Potential health effects

<table>
<thead>
<tr>
<th>Route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>no data available</td>
</tr>
<tr>
<td>Ingestion</td>
<td>no data available</td>
</tr>
<tr>
<td>Skin</td>
<td>no data available</td>
</tr>
<tr>
<td>Eyes</td>
<td>no data available</td>
</tr>
</tbody>
</table>

#### 11.2 Signs and Symptoms of Exposure:

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

#### 11.3 Additional Information:

Not applicable.

### 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:

No data available.

#### 12.6 Other adverse effects:

No data available.
Section 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:
Reagents must be disposed of in accordance with local regulations. Do not dispose of in wastewater. If appropriate, contact a licensed disposal company.

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:
No data available.

14.2 UN proper shipping name:
No data available.

14.3 Transport hazard class(es):
No data available.

14.4 Packing group:
No data available.

14.5 Environmental hazards:
No data available.

14.6 Special precautions for user:
No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
No data available.

Section 15: REGULATORY INFORMATION

This product is not regulated under US Federal and State Regulations, EU labeling Classification, Canada, and WHMIS Classification, with the exception of Sulfuric Acid that is present in low concentration in Stopping Solution (see below). Mixtures are in conformity with 98/79/EC IVDMD Directive.

US Federal and State Regulations

<table>
<thead>
<tr>
<th>SARA 313</th>
<th>Sulfuric Acid is subject to reporting requirements of Section 313, Title III of SARA.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA RG’s 40 CFR 302.4</td>
<td>Sulfuric Acid, Sodium Azide is listed.</td>
</tr>
</tbody>
</table>
California Proposition 65
Sulfuric Acid has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Ansh Labs advises you of the following warning: WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL
Sulfuric Acid, Sodium Azide is listed.

New Jersey Dept. of Health RTK List
Sulfuric Acid, Sodium Azide is listed.

Pennsylvania RTK
Sulfuric Acid, Sodium Azide is listed.

EU Labeling Classification
Preparation not classified.

Canada

WHMIS Classification
D1A - Poisonous and Infections Material: Division 1 - Immediate and Serious Toxic Effects: Very Toxic (Acute Inhalation Toxicity) E - Corrosive Material.

PIN
2796

Ingredients on Ingredient Disclosure List
Sulfuric Acid, Sodium Azide

Ingredients with unknown toxicological properties:
None

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS’ 1.0% w/w (0.1% for carcinogens) or EU’s ingredient specific concentrations required for reporting in Section 3.

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.

Changing against the last version:
Error corrected in section 1 of Safety Data Sheet.

Ansh Labs Safety Rating

<table>
<thead>
<tr>
<th>Flammability: 0</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health: 3</td>
<td>0= None</td>
</tr>
<tr>
<td>Reactivity with Water: 0</td>
<td>1=Slight</td>
</tr>
<tr>
<td>Contact: 0</td>
<td>2=Caution</td>
</tr>
<tr>
<td></td>
<td>3=Severe</td>
</tr>
</tbody>
</table>

Abbreviations and acronyms:
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)

* Data compared to the previous version altered

Key literature references and sources for data:
N/A

Hazard Classification codes and phrases used in this Safety Data Sheet as per regulation:

<table>
<thead>
<tr>
<th>Reg. 1272/2008</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H228</td>
<td>Flammable solid</td>
</tr>
<tr>
<td>H300</td>
<td>Fatal if swallowed</td>
</tr>
<tr>
<td>H301</td>
<td>Toxic if swallowed</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H311</td>
<td>Toxic in contact with skin</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage.</td>
</tr>
</tbody>
</table>
H315  Causes skin irritation  
H317  May cause an allergic skin reaction  
H318  Causes serious eye damage  
H319  Causes serious eye irritation  
H331  Toxic if inhaled  
H335  May cause respiratory irritation  
H400  Very toxic to aquatic life.  
H410  Very toxic to aquatic life with long lasting effects.

Dir. 67/548/CEE  
R11  Highly flammable  
R21  Harmful in contact with skin  
R22  Harmful if swallowed  
R23  Toxic by inhalation  
R24  Toxic in contact with skin  
R25  Toxic if swallowed  
R26  Very toxic by inhalation  
R27  Very toxic in contact with skin  
R28  Very toxic if swallowed  
R29  Contact with water liberates toxic gas.  
R30  Can become highly flammable in use  
R31  Contact with acids liberates toxic gas  
R32  Contact with acids liberates very toxic gas  
R33  Danger of cumulative effects  
R34  Causes burns  
R35  Causes severe burns  
R36  Irritating to eyes  
R37  Irritating to respiratory system  
R38  Irritating to skin  
R39  Danger of very serious irreversible effects  
R40  Limited evidence of a carcinogenic effect  
R41  Risk of serious damage to eyes  
R42  May cause sensitization by inhalation  
R43  May cause sensitization by skin contact  
R50  Very toxic to aquatic organisms  
R53  May cause long-term adverse effects in the aquatic environment  
C  Corrosive  
F  Highly Flammable  
Xi  Irritant  
Xn  Harmful  
N  Dangerous for the Environment

**WHMIS Classes**

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1A, D1B</td>
<td></td>
</tr>
</tbody>
</table>
|  | • **Division 1:** Materials Causing Immediate and Serious Toxic Effects  
|  |  
|  | o Subdivision A: Very Toxic Material  
|  | o Subdivision B: Toxic Material  
| D2B |  
|  | • **Division 2:** Materials Causing Other Toxic Effects (generally appear over time following one or several exposures)  
|  |  
|  | o Subdivision B: Toxic Material  
| E |  
|  | Corrosive Material  

**Advice for training:**
The product is intended for professional laboratory use.  
**Department issuing MSDS:** Regulatory Affairs Department / Document Control.  
**Contact:** TechSupport@AnshLabs.com