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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Trade name : AIA-PACK LIQUID
Product group : IN VITRO DIAGNOSTIC USE ONLY
Document no. : See annex

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Laboratory use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Tosoh Europe NV
Transportstraat 4
3980 Tessenderlo
Belgium
T +32 13 66 88 30, F +32 13 66 47 49
info.raqa.eu@tosoh.com

Manufacturer

Tosoh Corporation
2-2-1 Yaesu, Chuo-ku
104-0028 Tokyo
Japan

1.4. Emergency telephone number

Country/Area	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Not applicable.

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2.3. Other hazards

Other hazards : Results of PBT and vPvB assessment : Not applicable.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

Additional advice	: First aider: Pay attention to self-protection!. Concerning personal protective equipment to use, see section 8. Never give anything by mouth to an unconscious person. In case of doubt or persistent symptoms, consult always a physician. Show this safety data sheet to the doctor in attendance.
Inhalation	: Remove casualty to fresh air and keep warm and at rest. Give oxygen or artificial respiration if necessary. In case of doubt or persistent symptoms, consult always a physician.
Skin contact	: Remove contaminated clothing and shoes. Gently wash with plenty of soap and water. In case of doubt or persistent symptoms, consult always a physician.
Eyes contact	: Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses, if present and easy to do. Continue rinsing. In case of doubt or persistent symptoms, consult always a physician.
Ingestion	: Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get medical advice/attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects	: Not expected to present a significant hazard under anticipated conditions of normal use.
Inhalation	: May be harmful if inhaled. May cause respiratory irritation.
Skin contact	: May be harmful if absorbed through skin. May cause skin irritation.
Eyes contact	: May cause eye irritation.
Ingestion	: May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : carbon dioxide (CO₂), powder, alcohol-resistant foam, water spray.
 Unsuitable extinguishing media : Strong water jet.

5.2. Special hazards arising from the substance or mixture

Specific hazards : Not flammable. Heating will cause a rise in pressure with a risk of bursting.
 Hazardous decomposition products in case of fire : Unknown.

5.3. Advice for firefighters

Firefighting instructions : Evacuate area. Use water spray or fog for cooling exposed containers. Contain the extinguishing fluids by bunding. Prevent fire fighting water from entering the environment.
 Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus.
 Other information : Do not allow run-off from fire-fighting to enter drains or water courses. Dispose of waste in accordance with environmental legislation.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

For non-emergency personnel : Evacuate unnecessary personnel. Keep upwind. Provide adequate ventilation. Do not breathe vapours. Avoid contact with skin, eyes and clothing. Wear recommended personal protective equipment. Concerning personal protective equipment to use, see section 8.

6.1.2. For emergency responders

For emergency responders : Ensure procedures and training for emergency decontamination and disposal are in place. Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Provide adequate ventilation. Stop leak if safe to do so. Dam up the liquid spill. Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container for disposal. Recover large spills by pumping (use an explosion proof or hand pump). Place in a suitable container for disposal in accordance with the waste regulations (see Section 13). This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling

: Provide adequate ventilation. Do not breathe vapours. Avoid contact with skin, eyes and clothing. Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8. Take any precaution to avoid mixing with Incompatible materials, Refer to Section 10 on Incompatible Materials. Ensure proper process control to avoid excess waste discharge (temperature, concentration, pH, time). Avoid release to the environment.

Hygiene measures

: Keep good industrial hygiene. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feedingstuffs. Remove contaminated clothes. Separate working clothes from town clothes. Launder separately. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures

: Keep container tightly closed in a cool, well-ventilated place. Keep only in the original container. Do not store near or with any of the incompatible materials listed in section 10. Recommended storage temperature : 2-8°C.

Germany

German storage class (LGK)

: LGK 12 - Non-combustible liquids

7.3. Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods

Monitoring methods

Concentration measurement in air. Personal air monitoring .

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

Additional information

: Contains no substances with occupational exposure limit values. Recommended monitoring procedures :. Personal air monitoring. Room air monitoring

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

Engineering measure(s)	: Provide adequate ventilation. Organisational measures to prevent/limit releases, dispersion and exposure. See Section 7 for information on safe handling.
Personal protective equipment	: The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Hand protection	: Wear chemically resistant gloves (tested to EN374) . Suitable material: Not determined. Thickness : Not determined. Breakthrough time : Not determined. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.
Eye protection	: Use suitable eye protection (EN166): Safety glasses with side-shields
Body protection	: Wear suitable protective clothing. Lab coat
Respiratory protection	: Not required for normal conditions of use
Thermal hazard protection	: Not required for normal conditions of use. Use dedicated equipment.
Environmental exposure controls	: Do not allow to enter into surface water or drains. Comply with applicable Community environmental protection legislation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: No additional information available.
Appearance	: Liquid.
Odour	: No data available.
Odour threshold	: No additional information available
Melting / freezing point	: No additional information available
Freezing point	: Not available
Initial boiling point and boiling range	: No additional information available
Flammability	: Not flammable
Explosive properties	: Not applicable. The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.
Oxidising properties	: Not applicable. The classification procedure needs not to be applied because there are no chemical groups present in the molecule which are associated with oxidising properties.
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: No additional information available
Auto-ignition temperature	: No additional information available
Decomposition temperature	: No additional information available
pH	: No data available
Kinematic viscosity	: No data available
Dynamic viscosity	: No data available
Solubility	: Water: No additional information available

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Partition coefficient n-octanol/water (Log Kow) : Not available
 Partition coefficient n-octanol/water : No additional information available
 Vapour pressure : No additional information available
 Vapour pressure at 50°C : Not available
 Density : Not available
 Relative density : No additional information available
 Vapour density : No additional information available
 Particle characteristics : Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : No additional information available
 Additional information : No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable at ambient temperature and under normal conditions of use. Reference to other sections: 10.4 & 10.5.

10.2. Chemical stability

Stable under recommended storage conditions. (2-8°C). Observe the expiry date.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

See Section 7 for information on safe handling.

10.5. Incompatible materials

Strong oxidizing agents. See Section 7 for information on safe handling.

10.6. Hazardous decomposition products

Reference to other sections 5.2.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
 Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
 Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

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Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: No data available
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: No data available
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

AIA-PACK LIQUID	
Kinematic viscosity	No data available

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: Not applicable
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11.2.2. Other information

Other information	: Symptoms related to the physical, chemical and toxicological characteristics, For further information see section 4
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SECTION 12: Ecological information

12.1. Toxicity

Environmental properties	: According to the criteria of the European classification and labelling system, the substance/the product has not to be labelled as "dangerous for the environment".
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

12.2. Persistence and degradability

AIA-PACK LIQUID	
Persistence and degradability	No additional information available.

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12.3. Bioaccumulative potential

AIA-PACK LIQUID	
Partition coefficient n-octanol/water	No additional information available
Bioaccumulative potential	No additional information available.

12.4. Mobility in soil

AIA-PACK LIQUID	
Mobility in soil	No additional information available
Ecology - soil	No data available.

12.5. Results of PBT and vPvB assessment

AIA-PACK LIQUID	
Results of PBT assessment	Not applicable

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : Not applicable.

12.7. Other adverse effects

Additional information : No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Avoid release to the environment. Dispose of empty containers and wastes safely. See Section 7 for information on safe handling. Refer to manufacturer/supplier for information on recovery/recycling. Recycling is preferred to disposal or incineration. If recycling is not possible, eliminate in accordance with local valid waste disposal regulations. Handle contaminated packages in the same way as the substance itself. Dispose of contaminated materials in accordance with current regulations.

European waste catalogue (2001/573/EC, 75/442/EEC, 91/689/EEC) : MS-N13.00030010 - Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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ADR	IMDG	IATA	ADN	RID
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Special precautions for user : No data available

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Code: IBC : No data available.

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

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Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

Detergent Regulation (648/2004/EC): Labelling of contents

15.1.2. National regulations

France

Installations classées			
No ICPE	Désignation de la rubrique	Code Régime	Rayon
na	Not Applicable	na	na

No ICPE

Germany

Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV) : Is not subject to the Hazardous Incident Ordinance (12. BImSchV)
Technical Instructions on Air Quality Control (TA Luft) : Total dust.

Netherlands

Waterbezwaarlijkheid : B (4) - Weinig schadelijk voor in het water levende organismen
SZW-lijst van kankerverwekkende stoffen : None of the components are listed

15.2. Chemical safety assessment

Not applicable

SECTION 16: Other information

Indication of changes:

1.3	Details of the supplier of the safety data sheet	Modified	
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Abbreviations and acronyms:

	ADN = Accord Européen relatif au Transport International des Marchandises Dangereuses par voie de Navigation du Rhin ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route CLP = Classification, Labelling and Packaging Regulation according to 1272/2008/EC IATA = International Air Transport Association IMDG = International Maritime Dangerous Goods Code LEL = Lower Explosive Limit/Lower Explosion Limit UEL = Upper Explosion Limit/Upper Explosive Limit REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals
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	DNEL = DNEL = Derived No Effect Level
	LD50 = Median lethal dose
	N.O.S. = Not Otherwise Specified
	PNEC = Predicted No Effect Concentration
	STEL = Short term exposure limit
	TLV = Threshold limits
	TWA = time weighted average
	WGK = Wassergefährdungsklasse (Water Hazard Class under German Federal Water Management Act)
	ABM = Algemene beoordelingsmethodiek
	BTT = Breakthrough time (maximum wearing time)
	DMEL = Derived Minimal Effect level
	EC50 = Median Effective Concentration
	EL50 = Median effective level
	ErC50 = EC50 in terms of reduction of growth rate
	ErL50 = EL50 in terms of reduction of growth rate
	EWG = European waste catalogue
	LC50 = Median lethal concentration
	LL50 = Median lethal level
	NA = Not applicable
	NOEC = No observed effect concentration
	NOEL: no-observed-effect level
	NOELR = No observed effect loading rate
	NOAEC = No observed adverse effect concentration
	NOAEL = No observed adverse effect level
	OEL = Occupational Exposure Limits - Short Term Exposure Limits (STELs)
	Quantitative structure-activity relationship (QSAR)
	STOT = Specific Target Organ Toxicity
	VOC = Volatile organic compounds

Sources of key data used to compile the : Supplier information. ECHA (European Chemicals Agency). LOLI. datasheet

Training advice : Training staff on good practice.

Other information : Classification - Assessment method: CLP Calculation method (Article 9).

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

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EN

Product code	Designation
0020302	AIA-PACK 27.29 CALIBRATOR SET
0020502	AIA-PACK 27.29 SAMPLE DILUTING SOLUTION
0025521	ST AIA-PACK ACTH SAMPLE DILUTING SOLUTION
0020352	AIA-PACK AFP CALIBRATOR SET
0020552	AIA-PACK AFP SAMPLE DILUTING SOLUTION
0020359	AIA-PACK BMG CALIBRATOR SET
0025528	ST AIA-PACK BNP SAMPLE DILUTING SOLUTION
0020569	AIA-PACK CK-MB SAMPLE DILUTING SOLUTION
0025583	ST AIA-PACK C-Peptidell SAMPLE DILUTING SOLUTION
0025515	ST AIA-PACK cTnl 3rd-Gen SAMPLE DILUTING SOLUTION
0025517	ST AIA-PACK Cystatin C SAMPLE DILUTING SOLUTION
0025532	ST AIA-PACK D-Dimer SAMPLE DILUTING SOLUTION
0025322	ST AIA-PACK DHEA-S CALIBRATOR SET
0025522	ST AIA-PACK DHEA-S SAMPLE DILUTING SOLUTION
0020353	AIA-PACK FER CALIBRATOR SET
0020553	AIA-PACK FER SAMPLE DILUTING SOLUTION
0020592	AIA-PACK FOLATE SAMPLE DILUTING SOLUTION
0025311	ST AIA-PACK free PSA CALIBRATOR SET
0025511	ST AIA-PACK free PSA SAMPLE DILUTING SOLUTION
0020365	AIA-PACK FSH CALIBRATOR SET
0020565	AIA-PACK FSH SAMPLE DILUTING SOLUTION
0020373	AIA-PACK HBeAg CALIBRATOR SET
0020950	AIA-PACK HBV Antibody CONTROL SET
0025519	ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION
0020566	AIA-PACK HGH SAMPLE DILUTING SOLUTION
0025426	AIA-PACK Homocysteine CONTROL SET
0025325	ST AIA-PACK hsE2 CALIBRATOR SET
0025525	ST AIA-PACK hsE2 SAMPLE DILUTING SOLUTION
0025324	ST AIA-PACK iE2 CALIBRATOR SET
0025524	ST AIA-PACK iE2 SAMPLE DILUTING SOLUTION
0020395	AIA-PACK IgEII CALIBRATOR SET
0020595	AIA-PACK IgEII SAMPLE DILUTING SOLUTION
0020560	AIA-PACK IRI SAMPLE DILUTING SOLUTION
0025544	ST AIA-PACK KL-6 SAMPLE DILUTING SOLUTION
0025396	ST AIA-PACK LH II CALIBRATOR SET
0020596	AIA-PACK LH II SAMPLE DILUTING SOLUTION

Product code	Designation
0025597	ST AIA-PACK Myoglobin SAMPLE DILUTING SOLUTION
0025536	ST AIA-PACK Osteocalcin SAMPLE DILUTING SOLUTION
0020589	AIA-PACK OVCA SAMPLE DILUTING SOLUTION
0020562	AIA-PACK PAP SAMPLE DILUTING SOLUTION
0025533	ST AIA-PACK PIVKA-II SAMPLE DILUTING SOLUTION
0025542	ST AIA-PACK Presepsin SAMPLE DILUTING SOLUTION
0020555	AIA-PACK PRL SAMPLE DILUTING SOLUTION
0025340	ST AIA-PACK PROGIII CALIBRATOR SET
0025540	ST AIA-PACK PROGIII SAMPLE DILUTING SOLUTION
0025312	ST AIA-PACK PSA II CALIBRATOR SET
0025512	ST AIA-PACK PSA II SAMPLE DILUTING SOLUTION
0020514	AIA-PACK RBC FOLATE SAMPLE DILUTING SOLUTION
0025537	ST AIA-PACK SCC SAMPLE DILUTING SOLUTION
0025538	ST AIA-PACK SHBG SAMPLE DILUTING SOLUTION
0020585	AIA-PACK SLa SAMPLE DILUTING SOLUTION
0020358	AIA-PACK T4 CALIBRATOR SET
0020558	AIA-PACK T4 SAMPLE DILUTING SOLUTION
0025504	ST AIA-PACK Testosterone SAMPLE DILUTING SOLUTION
0025527	ST AIA-PACK Thyroglobulin SAMPLE DILUTING SOLUTION
0020709	AIA-PACK TgAb CONJUGATE
0020390	AIA-PACK TPOAb CALIBRATOR SET
0020490	AIA-PACK TPOAb CONTROL SET
0020708	AIA-PACK TPOAb CONJUGATE
0020590	AIA-PACK TPOAb/TgAb SAMPLE DILUTING SOLUTION
0020394	AIA-PACK TSH 3rd-Gen CALIBRATOR SET
0020594	AIA-PACK TSH 3rd-Gen SAMPLE DILUTING SOLUTION
0020382	AIA-PACK TT3 CALIBRATOR SET
0020582	AIA-PACK TT3 SAMPLE DILUTING SOLUTION
0025520	ST AIA-PACK β HCGII SAMPLE DILUTING SOLUTION