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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/designation : AIA-PACK Serie 1
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 uses
Use of the substance/mixture : Laboratory use

1.2.2. Uses advised against

No data 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
3-8-2 Shiba, Minato-ku
Tokyo 105-8623 - Japan
T + 81 3 5427 5181 - F + 81 3 5427 5220

1.4. Emergency telephone number

Country	Official advisory body	Address	Emergency number
Ireland	National Poisons Information Centre Beaumont Hospital	Beaumont Hospital Beaumont Road 9 Dublin	+353 1 809 21 66 (public, 8am - 10pm, 7/7) +353 01 809 2566 (Professionals, 24/7)
United Kingdom	National Poisons Information Service (Newcastle Centre) Regional Drugs and Therapeutics Centre, Wolfson Unit	Claremont Place Newcastle-upon-Tyne NE1 4LP Newcastle	0844 892 0111 (UK only, 24/7, healthcare professionals only)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Aquatic Chronic 3 H412

Full text of H statements : see section 16

2.2. Label elements

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

Signal word : -
Hazard statements (CLP) : H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP) : P273 - Avoid release to the environment.
P501 - Dispose of contents and container to an approved waste disposal plant
Extra phrases : EUH032 - Contact with acids liberates very toxic gas.

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2.3. Other hazards

Other hazards : PBT/vPvB data : not relevant .

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Reagent
(lyophilised)

Substance name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium azide	(CAS-No.) 26628-22-8 (EC-No.) 247-852-1 (EC Index) 011-004-00-7	0,25 - <2.25	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Additional advice : First aider: Pay attention to self-protection!. See also section 8 . Show this safety data sheet to the doctor in attendance. Treat symptomatically. In case of doubt or persistent symptoms, consult always a physician.

Inhalation : Provide fresh air. Give oxygen or artificial respiration if necessary.

Skin contact : Wash with plenty of water/....

Eyes contact : Flush with plenty of water.

Ingestion : Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

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

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray, Alcohol resistant foam, Carbon dioxide, Dry extinguishing powder.

Unsuitable extinguishing media : none.

5.2. Special hazards arising from the substance or mixture

Specific hazards : Do not allow run-off from fire-fighting to enter drains or water courses.

Hazardous decomposition products in case of fire : Unknown.

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5.3. Advice for firefighters

Firefighting instructions : Evacuate personnel to a safe area. Special protective equipment for firefighters. In case of fire: Wear self-contained breathing apparatus.

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 : Provide adequate ventilation. Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8. Avoid dust formation. Do not breathe dust. Avoid contact with eyes.

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. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Dispose of contaminated materials in accordance with current regulations.

6.4. Reference to other sections

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Provide adequate ventilation. Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8. Avoid contact with eyes. Do not breathe dust.

Hygiene measures : Keep good industrial hygiene. Wash hands and face before breaks and immediately after handling of the product. When using do not eat, drink or smoke. Take off contaminated clothing.

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. Protect from moisture. Do not store near or with any of the incompatible materials listed in section 10. Recommended storage temperature : 2-8°C.

7.3. Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium azide (26628-22-8)		
EU	IOELV TWA (mg/m ³)	0,1 mg/m ³
EU	IOELV STEL (mg/m ³)	0,3 mg/m ³
EU	Notes	Possibility of significant uptake through the skin
Austria	MAK (mg/m ³)	0,1 mg/m ³
Austria	MAK Short time value (mg/m ³)	0,3 mg/m ³
Bulgaria	OEL TWA (mg/m ³)	0,1 mg/m ³
Bulgaria	OEL STEL (mg/m ³)	0,3 mg/m ³
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	0,1 mg/m ³

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Sodium azide (26628-22-8)		
Croatia	KGVI (kratkotrajna granična vrijednost izloženosti) (mg/m³)	0,3 mg/m³
Cyprus	OEL TWA (mg/m³)	0,1 mg/m³
Cyprus	OEL STEL (mg/m³)	0,3 mg/m³
Czech Republic	Expoziční limity (PEL) (mg/m³)	0,1 mg/m³
Denmark	Grænseværdie (langvarig) (mg/m³)	0,1 mg/m³
Estonia	OEL TWA (mg/m³)	0,1 mg/m³
Estonia	OEL STEL (mg/m³)	0,3 mg/m³
Finland	HTP-arvo (8h) (mg/m³)	0,1 mg/m³
Finland	HTP-arvo (15 min)	0,3 mg/m³
France	VME (mg/m³)	0,1 mg/m³ (restrictive limit)
France	VLE (mg/m³)	0,3 mg/m³ (restrictive limit)
Germany	TRGS 900 Occupational exposure limit value (mg/m³)	0,2 mg/m³
Gibraltar	8h mg/m3	0,1 mg/m³
Gibraltar	Short-term mg/m3	0,3 mg/m³
Greece	OEL TWA (mg/m³)	0,3 mg/m³
Greece	OEL TWA (ppm)	0,1 ppm
Greece	OEL STEL (mg/m³)	0,3 mg/m³
Greece	OEL STEL (ppm)	0,1 ppm
Hungary	AK-érték	0,1 mg/m³
Hungary	CK-érték	0,3 mg/m³
Ireland	OEL (8 hours ref) (mg/m³)	0,1 mg/m³
Ireland	OEL (15 min ref) (mg/m3)	0,3 mg/m³
Italy	OEL TWA (mg/m³)	0,1 mg/m³
Italy	OEL STEL (mg/m³)	0,3 mg/m³
Latvia	OEL TWA (mg/m³)	0,1 mg/m³
Lithuania	IPRV (mg/m³)	0,1 mg/m³
Lithuania	TPRV (mg/m³)	0,3 mg/m³
Luxembourg	OEL TWA (mg/m³)	0,1 mg/m³
Luxembourg	OEL STEL (mg/m³)	0,3 mg/m³
Malta	OEL TWA (mg/m³)	0,1 mg/m³
Malta	OEL STEL (mg/m³)	0,3 mg/m³
Netherlands	Grenswaarde TGG 8H (mg/m³)	0,1 mg/m³
Netherlands	Grenswaarde TGG 15MIN (mg/m³)	0,3 mg/m³
Poland	NDS (mg/m³)	0,1 mg/m³
Poland	NDSch (mg/m³)	0,3 mg/m³
Portugal	OEL TWA (mg/m³)	0,1 mg/m³ (indicative limit value)
Portugal	OEL STEL (mg/m³)	0,3 mg/m³ (indicative limit value)
Portugal	OEL - Ceilings (mg/m³)	0,29 mg/m³
Portugal	OEL - Ceilings (ppm)	0,11 ppm (vapor)
Romania	OEL TWA (mg/m³)	0,1 mg/m³
Romania	OEL STEL (mg/m³)	0,3 mg/m³
Slovakia	NPHV (priemerná) (mg/m³)	0,1 mg/m³ (Sodium azide)
Slovakia	NPHV (Hraničná) (mg/m³)	0,3 mg/m³

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Sodium azide (26628-22-8)		
Slovenia	OEL TWA (mg/m ³)	0,1 mg/m ³
Slovenia	OEL STEL (mg/m ³)	0,3 mg/m ³
Spain	VLA-ED (mg/m ³)	0,1 mg/m ³ (indicative limit value)
Spain	VLA-EC (mg/m ³)	0,3 mg/m ³
Sweden	nivågränsvärde (NVG) (mg/m ³)	0,1 mg/m ³
Sweden	kortidsvärde (KTV) (mg/m ³)	0,3 mg/m ³
United Kingdom	WEL TWA (mg/m ³)	0,1 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	0,3 mg/m ³
Norway	Grenseverdier (AN) (mg/m ³)	0,1 mg/m ³
Norway	Grenseverdier (Korttidsverdi) (mg/m ³)	0,3 mg/m ³ (value from the regulation)
Switzerland	MAK (mg/m ³)	0,2 mg/m ³ (inhalable dust)
Switzerland	KZGW (mg/m ³)	0,4 mg/m ³ (inhalable dust)
Canada (Quebec)	PLAFOND (mg/m ³)	0,3 mg/m ³
Canada (Quebec)	PLAFOND (ppm)	0,11 ppm
USA - ACGIH	ACGIH Ceiling (mg/m ³)	0,29 mg/m ³
USA - ACGIH	ACGIH Ceiling (ppm)	0,11 ppm
USA - NIOSH	NIOSH REL (ceiling) (mg/m ³)	0,3 mg/m ³
USA - NIOSH	NIOSH REL (ceiling) (ppm)	0,1 ppm

Additional information : Recommended monitoring procedures :. Personal air monitoring. Room air monitoring

8.2. Exposure controls

Engineering measure(s)	: Provide adequate ventilation. Organisational measures to prevent /limit releases, dispersion and exposure. See also section 7.
Personal protective equipment	: Choose body protection according to the amount and concentration of the dangerous substance at the work place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Hand protection	: Protective gloves complying with EN 374. The selection of specific gloves for a specific application and time of use in a working area, should also take into account other factors on the working space, such as (but not limited to): other chemicals that are possibly used, physical requirements (protection against cutting/drilling, skill, thermal protection), and the instructions/specification of the supplier of gloves. Gloves must be inspected prior to use.
Eye protection	: Safety glasses with side-shields (EN 166)
Respiratory protection	: Not required for normal conditions of use. Provide appropriate exhaust ventilation at places where dust is formed. Effective dust mask (EN 149). When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. full face mask (DIN EN 136). Half-face mask (EN 140). In case of dust formation use respirator with filter: P1 (EN 143)
Thermal hazard protection	: Not required for normal conditions of use.
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	: Solid
Appearance	: Powder. (lyophilised).

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Colour	: Light beige.
Odour	: odourless.
Odour threshold	: Not applicable
pH	: Not applicable
Relative evaporation rate (butylacetate=1)	: Not applicable
Melting / freezing point	: Not applicable
Freezing point	: Not applicable
Initial boiling point and boiling range	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not determined
Flammability (solid, gas)	: Not applicable
Vapour pressure	: Not applicable
Vapour density	: Not applicable
Relative density	: Not determined
Solubility	: Water: Not determined
Partition coefficient n-octanol/water	: Not applicable
Kinematic viscosity	: Not applicable
Dynamic viscosity	: Not applicable
Explosive properties	: Not applicable.
Oxidising properties	: Not applicable.
Explosive limits	: Not applicable

9.2. Other information

Additional information	: No data available
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SECTION 10: Stability and reactivity

10.1. Reactivity

Stable at ambient temperature and under normal conditions of use.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

Sodium azide (26628-22-8)	
LD50/oral/rat	45 mg/kg
LD50/dermal/rabbit	20 mg/kg

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Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met.) pH: Not applicable
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met.) pH: Not applicable
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.)
Other information	: Symptoms related to the physical, chemical and toxicological characteristics : Reference to other sections: 4.2.

SECTION 12: Ecological information

12.1. Toxicity

Environmental properties	: Harmful to aquatic life with long lasting effects.
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Sodium azide (26628-22-8)	
LC50 fish 1	0,8 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss)
LC50 fish 2	0,7 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)

12.2. Persistence and degradability

AIA-PACK Serie 1	
Persistence and degradability	No data available.

12.3. Bioaccumulative potential

AIA-PACK Serie 1	
Partition coefficient n-octanol/water	Not applicable
Bioaccumulative potential	No data available.

12.4. Mobility in soil

AIA-PACK Serie 1	
Mobility in soil	No data available
Ecology - soil	No data available.

12.5. Results of PBT and vPvB assessment

AIA-PACK Serie 1	
Results of PBT assessment	No data available

12.6. Other adverse effects

Additional information	: No data available
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Handle with care. Safe handling: see section 7 . Do not allow to enter into surface water or drains. Dispose of contaminated materials in accordance with current regulations.
Additional information	: Delivery to an approved waste disposal company.
European waste catalogue (2001/573/EC, 75/442/EEC, 91/689/EEC)	: Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN 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
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

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

France

Installations classées :

Not applicable.

Germany

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Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

TA Luft : Total dust

Netherlands

Waterbezwaarlijkheid : A (3) Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

Not applicable

SECTION 16: Other information

Indication of changes:

2.2	Label elements	Modified	
15.1	Regulatory information	Modified	
16	Other information	Modified	

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
	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)

Sources of key data used to compile the datasheet : Additional information. Supplier.

Training advice : Training staff on good practice. Manipulations are to be done only by qualified and authorised persons.

Other information : Classification - Assessment method: CLP Calculation method (Article 9).
Physicochemical hazard assessment: Information given is based on tests on the mixture itself.

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Full text of H- and EUH-statements:

Acute Tox. 2 (Oral)	Acute toxicity Category 2
Aquatic Acute 1	Hazardous to the aquatic environment - Aquatic Acute 1
Aquatic Chronic 1	Hazardous to the aquatic environment - chronic hazard category 1
Aquatic Chronic 3	Hazardous to the aquatic environment - chronic hazard category 3
H300	Fatal if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Classification according to Regulation (EC) No. 1272/2008 [CLP]
Labelling according to Regulation (EC) No. 1272/2008 [CLP]

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ANNEX: AIA-PACK Serie 1

Revision Nr: 17/08/2021

EN

Product code	Designation
0025334	ST AIA-PACK 25-OH Vitamin D CALIBRATOR SET
0025221	ST AIA-PACK ACTH
0025252	ST AIA-PACK AFP
0020706	AIA-PACK B12 PRETREATMENT SET
0025328	ST AIA-PACK BNP CALIBRATOR SET
0025269	ST AIA-PACK CK-MB
0020387	AIA-PACK CORT CALIBRATOR SET
0025346	ST AIA-PACK CORT II CALIBRATOR SET
0025215	ST AIA-PACK cTnI 3rd-Gen
0025232	ST AIA-PACK D-Dimer
0025253	ST AIA-PACK FER
0020292	AIA-PACK FOLATE
0020392	AIA-PACK FOLATE CALIBRATOR SET
0020707	AIA-PACK FOLATE PRETREATMENT SET
0025211	ST AIA-PACK free PSA
0025265	ST AIA-PACK FSH
0025268	ST AIA-PACK FT4
0020368	AIA-PACK FT4 CALIBRATOR SET
0025208	ST AIA-PACK HBeAb
0025273	ST AIA-PACK HBeAg
0025210	ST AIA-PACK HBsAg2
0025219	ST AIA-PACK HCGII
0020366	AIA-PACK HGH CALIBRATOR SET
0025226	ST AIA-PACK Homocysteine
0025225	ST AIA-PACK hsE2
0025224	ST AIA-PACK iE2
0020360	AIA-PACK IRI CALIBRATOR SET
0025296	ST AIA-PACK LH II
0025297	ST AIA-PACK Myoglobin
0025397	ST AIA-PACK Myoglobin CALIBRATOR SET
0020389	AIA-PACK OVCA CALIBRATOR SET
0020362	AIA-PACK PAP CALIBRATOR SET
0025255	ST AIA-PACK PRL
0020355	AIA-PACK PRL CALIBRATOR SET
0025212	ST AIA-PACK PSAII

Product code	Designation
0025238	ST AIA-PACK SHBG
0025204	ST AIA-PACK Testosterone
0020291	AIA-PACK TgAb
0020290	AIA-PACK TPOAb
0025282	ST AIA-PACK TT3
0025220	ST AIA-PACK β HCGII