

Raw Materials to Accelerate Your **Molecular Diagnostics Kit Manufacturing**

Quality Matters

We at SAFC believe that the quality of raw materials is paramount in the successful manufacturing of an IVD product. However, quality requirements may vary depending on the intended use of a particular raw material or its supply chain requirements. Keeping your requirements in mind, SAFC has developed the following, "**Molecular Biology Grade Products**" that are highly suitable for production of molecular diagnostic products for the IVD industry.

Molecular Biology Grade Products – Molecular Biology Grade products are produced to meet the needs of SAFC customers who manufacture IVD products (reagents and kits), for use by molecular biology labs worldwide. These molecular biology grade raw materials have been tested and are free from contaminants such as DNase, RNase, and trace materials.

The products are broadly classified under four categories as described here.

Standard: SAFC products labeled as "Standard" are primarily intended for research use complying with ISO 9001 standards. These products are non-regulated raw materials and can be used in the early stages of product development.

Premium: Products labeled as "Premium" are pre-registered, non-regulated products that are intended for use in an industrial setting. The products comply with ISO 9001 standards and are suitable for use in the manufacture of IVD products.

Elite: SAFC products labeled as "Elite" are registered starting materials that could be used for the production of reagents and kits for the IVD and Biotech industry.

cGMP: Products labeled as cGMP are products produced to comply with the requirements of 21 CFR, and ISO 13485.

Enhanced Quality Profile for SAFC Diagnostics Products

Attributes	Standard	Premium	Elite	GMP/Compendia
Quality system controls	ISO 9001	ISO 9001	ISO 9001 + other Standard's elements	ICH Q7A, IPEC, 21 CFR, EDQM, 13485
Sourcing	Internal or external	Internal or external	Internal	Internal or strategic partner
Analytical methods	✓	✓	✓	✓
Certificate of Analysis	✓	✓	✓	✓
CCN-Standard	✓	✓	✓	✓
Specification	✓	✓	✓	✓
Certificate of Origin		✓	✓	✓
Expiry or retest date		✓	✓	✓
Vendor assessment		✓	✓	✓
CCN-Premium		✓	✓	✓
Critical Control Parameter (CCP)			✓	✓
QA batch review			✓	✓
Lot sample retained			✓	✓
CCN-Elite			✓	✓
Vendor management			✓	✓
Validation				✓

Unless specified all products listed below are Standard grade. Products labeled as Premium, Elite or cGMP are identified separately.

Product Name	Product Use	Product No.
Ammonium Acetate	For removal of untreated triphosphates	09688
Ammonium chloride	Buffer component	A9434
Ammonium sulfate	Buffer component	A4418
Bicine	Buffer component	83263
Boric Acid	Buffer component	B6768
BSA	Blocking agent	B4287
Cesium chloride	Highly purified Biochemical for use in DNA & RNA purification	C4036/ C3032
Dextran	Buffer ingredient for hybridization reactions	D8906
DL-Dithiothreitol	Reductant to enhance danaturation	43815
DMSO	Reagent to accelerate strand renaturation	D9170
DMSO	Cryoprotective agent for maintaining cell lines	D2438***
Glycerol	Storage buffer component	G5516
GLY-GLY/Glycine	Buffer component	50046
Guanidine HCL (available in different levels of purity)	Chaotropic agent for denaturation	50933/ G3272**
HEPES	Buffering agent useful in cell culture	H4034**
Imidazole	Buffer component	I5513
Lithium chloride	Precipitation of RNA	L9650
Lithium chloride (anhydrous)		62476
Magnesium acetate	Buffer component	M5661
Magnesium chloride (available in different configurations and purities)	Optimizing PCR reactions	M8787
Magnesium sulfate (available in different concentrations for varied applications)	Buffer component	83266
Maltose	Bioreagent	63423
Manganese chloride solution	Bioreagent	M1787
Manganese chloride tetrahydrate	Buffer component	63535
MES	Bioreagent	M2933/ M3058**
MOPS	Bioreagent	M3183
Nitro blue tetrazolium blue	Colorimetric detection	N6639
N- lauryl sarcosine	Used in cell lysis step for RNA purification	L9150*

Product Name	Product Use	Product No.
PBS	Bioreagent	P5368
Phenol	Bioreagent	77608/P1037
PIPES	Buffer component	80635
Polyvinyl pyrrolidone	Component of Denhardt's solution	81438
Polyvinyl pyrrolidone	Component of Denhardt's solution (Nucleic acid hybridization tested)	P5288
Potassium acetate	Bioreagent	60035/P1190
Potassium chloride	Buffer component in the preparation of PBS	60128/ P9541
Potassium phosphate	Bioreagent	P9791
Potassium phosphate	Bioreagent (available as a dibasic trihydrate)	P9666
Proteinase K	For denaturation of proteins	P4850
Proteinase K (lyophilized)	For denaturation of proteins	P2308**
Saponin	Bioreagent	47036
Sodium chloride	Buffer component	71376
Sodium chloride	Buffer component (tested free of Dnase and other contaminants)	S3014
Sodium citrate	Buffer component	C8532/71402
Sodium hydroxide solution	Bioreagent	72068
Sodium lauryl sulfate	Bioreagent	71725
Sodium phosphate	Bioreagent	S3264
Sorbitol	Bioreagent	S6021
Spermidine	For purification of DNA binding proteins	85558/ S0266
Sucrose	Bioreagent	84097/S0389*
TAPS	Bioreagent Buffers	T3516**
TES	Bioreagent Buffers	T5691
Tetraethylammonium chloride	Bioreagent	86614
Tricine	Bioreagent Buffers	T5816**
TRIS	Buffer	T6066**
TRIS-HCL	Buffer	T5941**
Triton X-100	Surfactant	93426/T8787
TWEEN 20	Non ionic surfactant	P9416
TWEEN 80	Non ionic surfactant	P5188
UREA	For denaturation of proteins	51456/U5378

* Available as a "Premium" product

** Available as an "Elite" product

*** Available as a "cGMP" product