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## SOP APPENDIX



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Document Title:

## RAW MATERIAL SPECIFICATION, CMRL 1066, SUPPLEMENTED, CIT MODIFICATIONS

### 1.0 Requirements:

TEST	METHOD	REQUIREMENT
<b>Identity</b>	Visual Inspection	Container label and Certificate of Analysis must specify: "CMRL 1066, Supplemented, CIT Modifications" and must have same lot number.
<b>Vendor</b>	Visual Inspection	Mediatech, Inc., Cat. No. 98-304, or other qualified vendor.
<b>Review of Vendor's Certificate of Analysis</b>	Visual Inspection	All requirements on the Certificate of Analysis must be met. pH: 7.3 ± 0.1 @ 20 to 25°C Osmolality: 300 ± 20 mOsm/kg H <sub>2</sub> O Endotoxin: ≤ 0.5 EU/mL Sterility : Pass Mycoplasma: Tested Negative USP Safety Test <88>: Pass Cholesterol Source: Animal Source The Certificate of Analysis must be signed and dated.

### 2.0 Storage

2°C to 8°C

### 3.0 Formulation:

Chemical	Concentration (g/L)	Chemical	Concentration (g/L)
Insulin, Human, Recombinant	0.00625000	L-Alanyl-L-Glutamine	0.43440000
CaCl <sub>2</sub> , anhydrous	0.20000000	Biotin	0.00001000
MgSO <sub>4</sub> , anhydrous	0.09970000	Folic Acid	0.00001000
Na Acetate, anhydrous	0.05000000	Riboflavin	0.00001000
NaH <sub>2</sub> PO <sub>4</sub> H <sub>2</sub> O	0.14000000	Coccarboxylase	0.00100000
ZnSO <sub>4</sub> 7 H <sub>2</sub> O	0.00480000	Li <sub>3</sub> Coenzyme A 2 H <sub>2</sub> O	0.00250000
Dextrose	1.00000000	Cozymase	0.00700000
KCl	0.40000000	Na <sub>2</sub> FAD	0.00100000
NaCl	5.19300000	TPN, Na	0.00100000
NaHCO <sub>3</sub>	2.20000000	UTP, Na <sub>3</sub> X H <sub>2</sub> O	0.00100000
Na Gluconate H <sub>2</sub> O	0.00420000	D-Ca-Pantothenate	0.00001000
Selenious Acid	0.00000625	Choline Chloride	0.00050000
L-Alanine	0.02500000	i-Inositol	0.00005000
L-Arginine HCl	0.07000000	Nicotinic Acid	0.00002500
L-Aspartic Acid	0.03000000	Nicotinamide	1.20000000
L-Cysteine HCl H <sub>2</sub> O	0.26000000	PABA	0.00005000

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<b>Document Title:</b>				
<b>RAW MATERIAL SPECIFICATION CMRL 1066, SUPPLEMENTED</b>				

<b>Chemical</b>	<b>Concentration (g/L)</b>	<b>Chemical</b>	<b>Concentration (g/L)</b>
L-Cystine 2 HCl	0.02600000	Pyridoxine HCl	0.00005000
L-Glutamic Acid	0.07500000	Na Pyruvate	0.55000000
Glycine	0.05000000	Thiamine HCl	0.00001000
L-Histidine HCl H <sub>2</sub> O	0.02000000	Linoleic Acid	0.00535000
Hydroxy-L-Proline	0.01000000	Human Transferrin (iron poor)	0.00625000
L-Isoleucine	0.02000000	Glutathione (reduced)	0.01000000
L-Leucine	0.06000000	Thymidine	0.01000000
L-Lysine HCl	0.07000000	2-D-Adenosine	0.01000000
L-Methionine	0.01500000	2-D-Cytidine HCl	0.01000000
L-Phenylalanine	0.02500000	2-D-Guanosine	0.01000000
L-Proline	0.04000000	5-Methyl-2'-Deoxycytidine	0.00010000
L-Serine	0.02500000	Cholesterol	0.00020000
L-Threonine	0.03000000	Tween 80	0.00500000
L-Tryptophan	0.01000000	HEPES	5.95000000
L-Valine	0.02500000	NSA-Human, 25%	5.00000000 mL
L-Tyrosine 2 Na 2 H <sub>2</sub> O	0.05800000		