## ATTACHMENT 1 (Page 1 of 2)
## Room Classifications/Monitoring Frequency

**FILL/FINISH SUITES:**

| Room Number | Room Classification | Room Description | Monitoring Type | Monitoring Frequency | Room Condition* |
|---|---|---|---|---|---|
| 141/141LAP | ISO 8 / ISO 8 (LAP Viable) / ISO 5 (LAP Total Particulate) | GMP Support (Glasswash) | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 142/142L | ISO 6 / ISO 5 | Filling Suite 1 | Total Particulates / Air Viables / Surface Viables | When in use and not less than **twice** per week | D or S |
| 143 | ISO 7 (Zone 1 and 2) / ISO 6 (Zone 3) | Aseptic Fill/Finish Gowning Room | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 144 | ISO 6 | Aseptic Staging Room | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 145 | ISO 8 | Aseptic Core Exit Room | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 146/146T | ISO 6 / ISO 5 | Filling Suite 2 | Total Particulates / Air Viables / Surface Viables | When in use and not less than **twice** per week | D or S |
| 147/147T | ISO 6 / ISO 5 | Filling Suite 3 | Total Particulates / Air Viables / Surface Viables | When in use and not less than **twice** per week | D or S |
| 147A | ISO 7 | Filtration Staging Suite | Total Particulates / Air Viables / Surface Viables | When in use and not less than **twice** per week | D or S |
| 157 | ISO 8 (West) / ISO 7 (East) | Gowning/Material Transfer Room | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 158 | ISO 7 / ISO 6 | Staging Room | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 159 | ISO 7 | Formulation Room | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 162/163/ 147B | ISO 8 | Ante-Room / Manufacturing Supplies / Lyophilizer Room | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 164/164T | ISO 8 / ISO 7 | Formulation 1 | Total Particulates / Air Viables / Surface Viables | When in use and not less than once per week | D or S |
| 165/165T | ISO 8 / ISO 7 | Formulation 2 | Total Particulates / Air Viables / Surface Viables | When in use and not less than once per week | D or S |

*Condition that each room must be in during environmental sampling. 'D' means dynamic condition, 'S' means static condition. See section 3.0 for definitions of dynamic and static.

## ATTACHMENT 1 (Page 2 of 2)
## Room Classifications/Monitoring Frequency

**BMG SUITES:**

| Room Number | Room Classification | Room Description | Monitoring Type | Monitoring Frequency | Room Condition* |
|---|---|---|---|---|---|
| 119 | ISO 8 | Gowning | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 126/127/127L | ISO 7 / ISO 7 / ISO 5 | Ante Room / Cell Banking 1 | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week for room Each use for hood | D or S |
| 128/129/129L | ISO 8 / ISO 8 / ISO 6 | Ante Room / Fermentation 1 | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 130/131/131L | ISO 7 / ISO 7 / ISO 6 | Ante Room / Purification 1 | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week for room Each use for hood | D or S |
| 132/133/133L | ISO 7 / ISO 7 / ISO 6 | Ante Room / Purification 2 | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 134/135/135L | ISO 8 / ISO 8 / ISO 6 | Ante Room / Fermentation 2 | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 136 | ISO 8 | Buffer Prep 1 | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 137 | ISO 8 | Media Prep | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 138/139 | ISO 8 | Hallway | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 140/150/151 | ISO 8 | Circulation Hallway / Airlock | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |
| 152/156 | ISO 7 | Ante Room / Manufacturing 1 | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 154/153/153L | ISO 7 / ISO 7 / ISO 6 | Exit Room / Purification 3 | Total Particulates / Air Viables / Surface Viables | Not less than **twice** per week | D or S |
| 160/161 | ISO 8 | Ante-Room / Buffer Prep 2 | Total Particulates / Air Viables / Surface Viables | Not less than once per week | D or S |

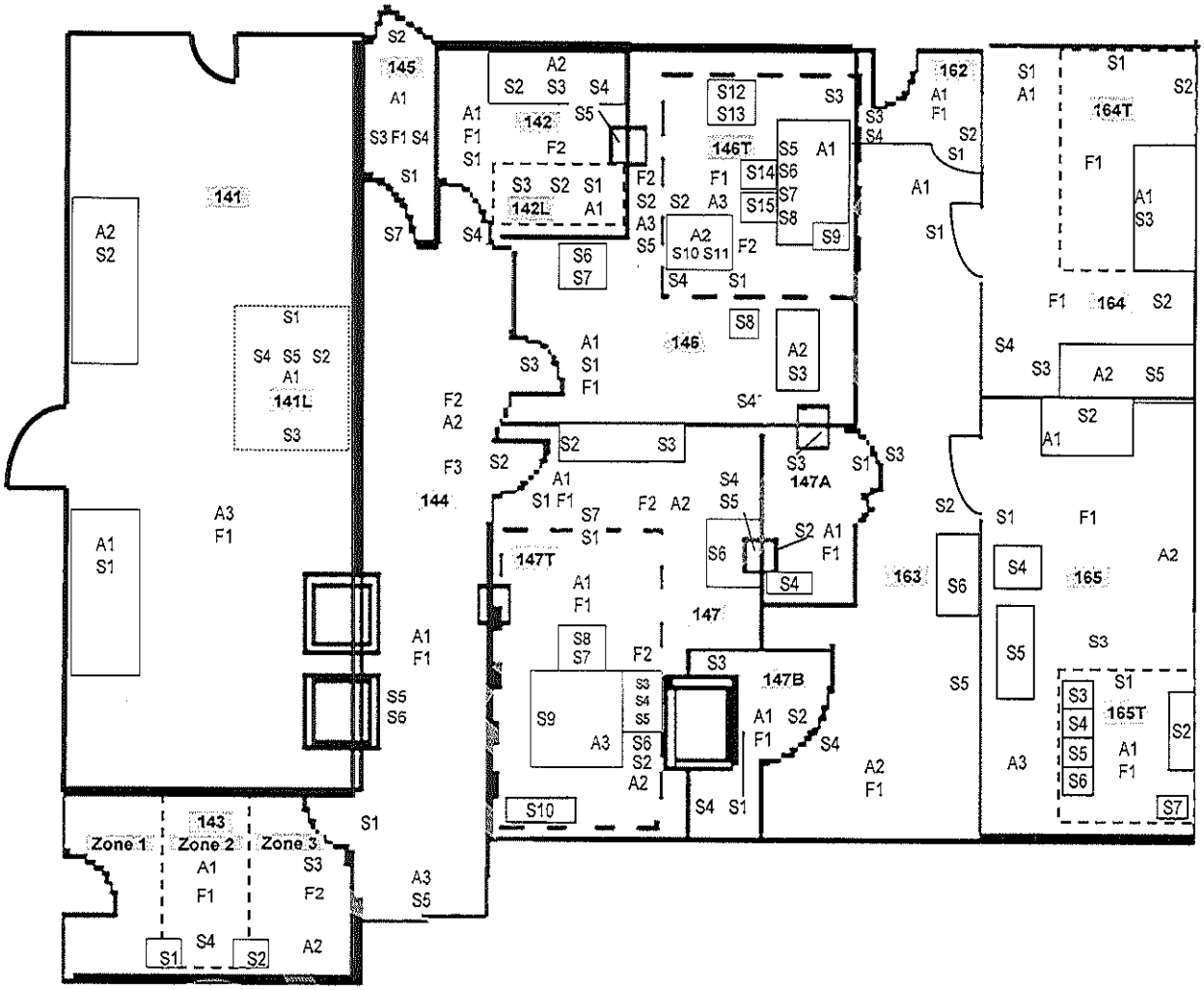
## ATTACHMENT 2
## Alert and Action* Levels (Standardized)

| Sample Type | | ISO 5 (Class 100) | | ISO 6 (Class 1,000) | | ISO 7 (Class 10,000) | | ISO 8 (Class 100,000) | |
|---|---|---|---|---|---|---|---|---|---|
| | | Alert | Action | Alert | Action | Alert | Action | Alert | Action |
| Air Viables: R2S / Settling Plates (CFU/plate) | | N/A | ≥ 1 CFU | | | | | | |
| Air Viables: MAS 100 / SAS-180 (CFU/m³) | | N/A | ≥ 1 | >2 | >3 | >5 | >10 | >25 | >50 |
| AGAR CONTACT (CFU/25 cm²) | Surface | N/A | ≥ 1 | >2 | >3 | >3 | >5 | >12 | >25 |
| | Floor | >2 | >3 | >2 | >3 | >7 | >10 | >12 | >25 |
| Personnel Monitoring*[1] (CFU/25 cm²) | Fingertips | N/A | ≥ 1 | | | | | | |
| | Forearm, Forehead, Mask | >2 | >3 | | | | | | |
| | Zipper, Waist, Shoulder, Calf | >3 | >5 | | | | | | |
| Total Particulates (0.5-µm particles) | | >1250 particles/$m^3$ | >2500 particles/$m^3$ | >5000 particles/$m^3$ | >10000 particles/$m^3$ | >1000 particles/$ft^3$ | >2000 particles/$ft^3$ | >2500 particles/$ft^3$ | >5000 particles/$ft^3$ |
| Total Particulates (5.0-µm particles) | | >10 particles/$m^3$ | >20 particles/$m^3$ | >500 particles/$m^3$ | >1000 particles/$m^3$ | >50 particles/$ft^3$ | >80 particles/$ft^3$ | >125 particles/$ft^3$ | >250 particles/$ft^3$ |

* Action Levels are set at or below the regulatory requirements based on historical data, ISO14644-1, USP, and EudraLex Annex 1.

*[1] If growth is recovered from ≥3 sites or total recovered is ≥12 CFU, an action level has been reached.

## ATTACHMENT 5 (Page 1 of 3)
## Ajinomoto Althea Fill/Finish Sampling Sites



## ATTACHMENT 5 (Page 2 of 3)
## Ajinomoto Althea Fill/Finish Sampling Sites

| Room | Site |
|---|---|
| 141 (ISO 8) | A1: Countertop South |
| | A2: Countertop North |
| | A3: Center Room |
| | S1: Countertop South |
| | S2: Countertop North |
| | F1: Floor Center |
| 141L (LAP viable: ISO 8, LAP total particulate: ISO 5) | A1: Center |
| | S1: North Curtain |
| | S2: East Curtain |
| | S3: South Curtain |
| | S4: West Curtain |
| | S5: Steel Counterop |
| 142 (ISO 6) | A1: Door to Room 144 |
| | A2: Table Center |
| | S1: Door to 144 |
| | S2: Table West |
| | S3: Table Middle |
| | S4: Table East |
| | S5: Pass-Thru |
| | F1: Floor near Door to 144 |
| | F2: Floor at Center Hood |
| 142L (ISO 5) | A1: Center |
| | S1: Hood Bench Left |
| | S2: Hood Bench Middle |
| | S3: Hood Bench Right |
| 143 (ISO 7, Zone 3: ISO 6) | A1: Zone 2 Center |
| | A2: Zone 3 Center |
| | S1: Bench Zone 2 |
| | S2: Bench Zone 3 |
| | S3: Door to 144 |
| | S4: Shelf/Rack Zone 2 |
| | F1: Floor Zone 3 |
| 144 (ISO 6) | A1: Autoclave/ DP Oven Center |
| | A2: Door to 146/147 Center |
| | A3: Door to 143/158 Center |
| | S1: Door to 143 |
| | S2: Door to 147 |
| | S3: Door to 146 |
| | S4: Door to 142 |
| | S5: Autoclave Door |
| | S6: Autoclave Dolly |
| | S7: Shelf/Rack |
| | F1: Floor at Autoclave |
| | F2: Floor at 146 |
| | F3: Floor at 147 |
| 145 (ISO 7) | A1: North Exit |
| | S1: Door to 144 |
| | S2: Door to 151 |

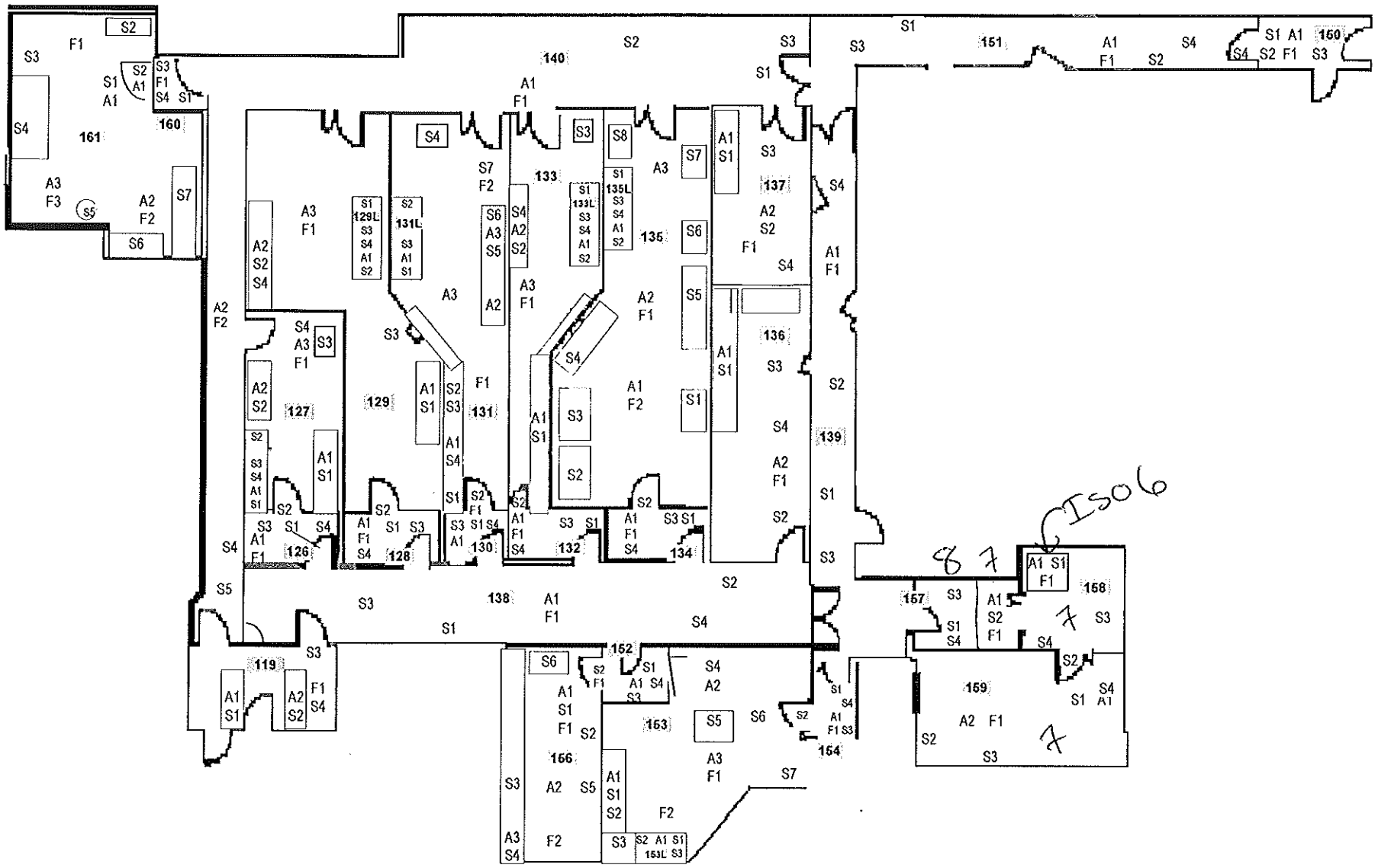
| Room | Site |
|---|---|
| 145 (ISO 7) | S3: West Wall |
| | S4: East Wall |
| | F1: Floor Center |
| 146 (ISO 6) | A1: By Door to 144 |
| | A2: Table Center |
| | A3: North Center |
| | S1: Door to 144 |
| | S2: North West Wall |
| | S3: Table Weight Check Area |
| | S4: South East Wall |
| | S5: Outside of Tent Curtain |
| | S6: Floor Scale |
| | S7: Floor Scale Keypad |
| | S8: Chair |
| | F1: Floor by Door to 144 |
| | F2: Floor by Tent Entrance |
| 146T (ISO 5) | A1: Tent Table Center |
| | A2: Crimp Table Center |
| | A3: Center Tent |
| | S1: South Curtain |
| | S2: West Curtain |
| | S3: North Wall |
| | S4: Tent Post |
| | S5: Tent Table Left |
| | S6: Tent Table Middle |
| | S7: Tent Table Right |
| | S8: N2 Unit Door |
| | S9: N2 Unit Inside Base |
| | S10: Crimp Table Left |
| | S11: Crimp Table Right |
| | S12: Floor Scale |
| | S13: Floor Scale Keypad |
| | S14: Chair |
| | S15: Chair |
| | F1: Floor Center |
| | F2: Floor Under Crimp Table |
| 147 (ISO 6) | A1: By Door to 144 |
| | A2: East Center |
| | S1: Door to 144 |
| | S2: Table West |
| | S3: Table East |
| | S4: Door to 147A |
| | S5: 147A Pass-Thru Door Handle |
| | S6: Filtration Table |
| | S7: Outside North Tent Curtain |
| | F1: Floor by Door to 144 |
| | F2: Floor at East Center |

## ATTACHMENT 5 (Page 3 of 3)
## Ajinomoto Althea Fill/Finish Sampling Sites

| Room | Site |
|---|---|
| 147T (ISO 5) | A1: Filler Vial Exit |
| | A2: Filler Vial Entry |
| | A3: Inside Filler |
| | S1: Tent North Curtain |
| | S2: Lyophilizer Center |
| | S3: Filler Cabinet East |
| | S4: Filler Keypad Right |
| | S5: Filler Keypad Left |
| | S6: Filler Door Above Cabinet |
| | S7: Filler Window near Vial Exit |
| | S8: Filler Vial Exit |
| | S9: Door Handle to Stopper/Seal Bowl |
| | S10: EM Cart Inside Tent |
| | F1: Floor at Vial Exit |
| | F2: Floor at Filler Keypad |
| 147A (ISO 7) | A1: Center Room |
| | S1: Door to 163 |
| | S2: Pass-Thru to 147 |
| | S3: Pass-Thru to 146 |
| | S4: Table |
| | F1: Floor Center |
| 162 (ISO 8) | A1: Center Room |
| | S1: Door to Room 163 |
| | S2: East Wall |
| | S3: West Wall |
| | S4: Bench |
| | F1: Floor |
| 163 (ISO 8) | A1: Center North |
| | A2: Center South |
| | S1: Door to 164 |
| | S2: Door to 165 |
| | S3: Door to 147A |
| | S4: Door to 147B |
| | S5: Cart/Rack |
| | S6: Table |
| | F1: Floor |
| 147B (ISO 8) | A1: Center Room |
| | S1: Lyophilizer Door Handle |
| | S2: Door to 163 |
| | S3: North Wall |
| | S4: South Wall |
| | F1: Floor |

| Room | Site |
|---|---|
| 164 (ISO 8) | A1: North Center |
| | A2: South Center |
| | S1: North Wall |
| | S2: East Wall |
| | S3: South Wall |
| | S4: West Wall/Door |
| | S5: Table Outside Tent |
| | F1: Floor Center |
| 164T (ISO 7) | A1: Tent Center |
| | S1: North Wall |
| | S2: East Wall |
| | S3: Tent Table |
| | F1: Floor Tent Center |
| 165 (ISO 8) | A1: NW Center |
| | A2: West Center |
| | A3: South Center |
| | S1: Door to 163 |
| | S2: Table |
| | S3: Outside of Curtain |
| | S4: Particle Containment Unit |
| | S5: Rack/Cart |
| | F1: Floor Center |
| 165T (ISO 7) | A1: Center |
| | S1: Inside of Curtain |
| | S2: Table |
| | S3: Mixer |
| | S4: Chiller |
| | S5: MicroFluidizer |
| | S6: Sonicator |
| | S7: Floor Scale Keypad |
| | F1: Floor Center |

## ATTACHMENT 6 (Page 1 of 4)
## Ajinomoto Althea BMG Sampling Sites



## ATTACHMENT 6 (Page 2 of 4)
## Ajinomoto Althea BMG Sampling Sites

| Room | Site |
|---|---|
| 119 (ISO 8) | A1: Pre-Shelves |
| | A2: Post-Bench |
| | S1: Pre-Shelves |
| | S2: Post-Bench |
| | S3: Door to 138 |
| | S4: East Wall |
| | F1: Floor Clean Side |
| 126 (ISO 7) | A1: Center Room |
| | S1: Door to 138 |
| | S2: Door to 127 |
| | S3: West Wall |
| | S4: East Wall |
| | F1: Floor Clean Side |
| 127 (ISO 7) | A1: Countertop East |
| | A2: Countertop West |
| | A3: Center Room |
| | S1: Countertop East |
| | S2: Countertop West |
| | S3: Shaker |
| | S4: Wall |
| | F1: Floor Center |
| 127L (ISO 5) | A1: Center |
| | S1: BSC Left |
| | S2: BSC Right |
| | S3: BSC Back |
| | S4: BSC Bench |
| 128 (ISO 8) | A1: Center Room |
| | S1: Door to 138 |
| | S2: Door to 129 |
| | S3: West Wall |
| | S4: East Wall |
| | F1: Floor Clean Side |

| Room | Site |
|---|---|
| 129 (ISO 8) | A1: Countertop East |
| | A2: Countertop West |
| | A3: Center Room |
| | S1: Countertop East |
| | S2: Countertop West |
| | S3: Pass-thru |
| | S4: Wall |
| | F1: Floor Center |
| 129L (ISO 6) | A1: Center |
| | S1: BSC Left Wall |
| | S2: BSC Right Wall |
| | S3: BSC Back |
| | S4: BSC Bench |
| 130 (ISO 7) | A1: Center Room |
| | S1: Door to 138 |
| | S2: Door to 131 |
| | S3: West Wall |
| | S4: East Wall |
| | F1: Floor Clean Side |
| 131 (ISO 7) | A1: Center South |
| | A2: Table East |
| | A3: Counter North |
| | S1: Door Handle to 130 |
| | S2: Wall by Sink |
| | S3: Counter |
| | S4: Cart |
| | S5: Table East |
| | S6: Toolbox |
| | S7: Door Handle to 140 |
| | F1: Floor Center South |
| | F2: Floor Center North |
| 131L (ISO 6) | A1: LAF |

| Room | Site |
|---|---|
| 131L (ISO 6) | S1: LAF Right |
| | S2: LAF Left |
| | S3: LAF Bench |
| 132 (ISO 7) | A1: Center Room |
| | S1: Door to 138 |
| | S2: Door to 133 |
| | S3: North Wall |
| | S4: South Wall |
| | F1: Floor Clean Side |
| 133 (ISO 7) | A1: Countertop South |
| | A2: Countertop North |
| | A3: Center Room |
| | S1: Countertop South |
| | S2: Countertop North |
| | S3: Cart/ Rack |
| | S4: Wall |
| | F1: Floor Center |
| 133L (ISO 6) | A1: Center |
| | S1: BSC Left |
| | S2: BSC Right |
| | S3: BSC Back |
| | S4: BSC Bench |
| 134 (ISO 8) | A1: Center Room |
| | S1: Door to 138 |
| | S2: Door to 135 |
| | S3: West Wall |
| | S4: East Wall |
| | F1: Floor Clean Side |
| 135 (ISO 8) | A1: Center South |
| | A2: Center |
| | A3: Center North |
| | S1: Cabinet |

## ATTACHMENT 6 (Page 3 of 4)
## Ajinomoto Althea BMG Sampling Sites

| Room | Site |
|---|---|
| 135 (ISO 8) | S2: CIP Cart Controller |
| | S3: Fermentor |
| | S4: Wall by Sink |
| | S5: Counter |
| | S6: Refrigerator |
| | S7: Centrifuge |
| | S8: Shaker |
| | F1: Floor by Sink |
| | F2: Floor Center |
| 135L (ISO 6) | A1: BSC |
| | S1: BSC Left Wall |
| | S2: BSC Right Wall |
| | S3: BSC Back |
| | S4: BSC Bench |
| 136 (ISO 8) | A1: Countertop |
| | A2: Center Room |
| | S1: Countertop |
| | S2: Door to 138 |
| | S3: Door to 139 |
| | S4: Rack |
| | F1: Floor Center |
| 137 (ISO 8) | A1: Countertop |
| | A2: Center Room |
| | S1: Countertop |
| | S2: Door to 139 |
| | S3: Door to 140 |
| | S4: Autoclave Door |
| | F1: Floor Center |
| 140 | A1: By Door to 133 |
| | A2: By Door to 127 |

| Room | Site |
|---|---|
| 140 | S1: Door Handle to 151 |
| | S2: Storage Unit |
| | S3: North East Wall |
| | S4: South West Wall |
| | S5: Door Handle to 118 |
| | F1: Floor By Purification |
| | F2: Floor By Cell Banking |
| 138, 139, 150, 151 (ISO 8) | A1: Center Room |
| | S1: Wall 1 |
| | S2: Wall 2 |
| | S3: Door 1 |
| | S4: Door 2 |
| | F1: Floor Center |
| 152 (ISO 7) | A1: Center Room |
| | S1: Door to Hallway 138 |
| | S2: Door to Room 156 |
| | S3: Cabinet/Rack |
| | S4: East Wall |
| | F1: Floor by Door to Room 156 |
| 153 (ISO 7) | A1: Center West Counter |
| | A2: Northeast Corner |
| | A3: Center Room |
| | S1: West Wall |
| | S2: Countertop |
| | S3: Refrigerator Door |
| | S4: Shelf Rack |
| | S5: Stainless Steel Cabinet |
| | S6: Door to Room 154 |
| | S7: Sink |
| | F1: Center Floor |

| Room | Site |
|---|---|
| 153 (ISO 7) | F2: Floor by Hood/Refrigerator |
| 153L (ISO 6) | A1: Center |
| | S1: Hood Left |
| | S2: Hood Right |
| | S3: Hood Bench |
| 154 (ISO 7) | A1: Center Room |
| | S1: Door to Hallway 139 |
| | S2: Door to Room 153 |
| | S3: Cabinet / Rack |
| | S4: East Wall |
| | F1: Floor by Door to Room 153 |
| 156 (ISO 7) | A1: By Door to 152 |
| | A2: Center Room |
| | A3: Counter South Side |
| | S1: Door to 152 |
| | S2: East Wall |
| | S3: Wall Above Sink |
| | S4: Counter South Side |
| | S5: Hoist |
| | S6: Cart/Rack/Cabinet |
| | F1: Center South Side |
| | F2: By Door to 152 |
| 157 (ISO 8,ISO 7) | A1: ISO 7 Side |
| | S1: Door to Hallway 139 |
| | S2: Door to Room 158 |
| | S3: Rack |
| | S4:South Wall |
| | F1: Floor ISO 7 Side |
| 158 (ISO 7, ISO 6) | A1: ISO 6 Side |
| | S1: Door to Room 144 |

## ATTACHMENT 6 (Page 4 of 4)
## Ajinomoto Althea BMG Sampling Sites

| Room | Site |
|---|---|
| 158 (ISO 7, ISO 6) | S2: Door to Room 159 |
| | S3: East Wall |
| | S4: South Wall |
| | F1: Floor ISO 6 Side |
| 159 (ISO 7) | A1: North East |
| | A2: South West |
| | S1: Door to Room 158 |
| | S2: West Wall |
| | S3: South Wall |
| | S4: East Wall |
| | F1: Floor |
| 160 (ISO 8) | A1: Center Room |
| | S1: Door to Hall 140 |
| | S2: Door to Room 161 |
| | S3: Wall |
| | S4: Rack |
| | F1: Floor Center |
| 161 (ISO 8) | A1: By Door to 160 |
| | A2: By Sink Center |
| | A3: South End Center |
| | S1: Door to 160 |
| | S2: Cabinet |
| | S3: Wall |
| | S4: Depyrogenation Oven |
| | S5: Pole |
| | S6: Wall Above Sink |
| | S7: Counter |
| | F1: Floor North Center |
| | F2: Floor by Sink |
| | F3: Floor South Center |