

SOP-0544

AJINOMOTO ALTHEA, INC.

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BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

ATTACHMENT 1
ROOM CLASSIFICATIONS/MONITORING TYPE AND FREQUENCY

Room Number	Room Classification	Room Description	Monitoring Type	Monitoring Frequency	Room Condition*
504/505	ISO 8	Anteroom / Fill Finish Glasswash	Total Particulate / Air Viable / Surface Viable	Not less than once per week	D or S
507	ISO 8	Glasswash Closet	Total Particulate / Air Viable / Surface Viable	Not less than once per week	D or S
508	ISO 8	Material and Equipment Anteroom	Total Particulate / Air Viable / Surface Viable	Not less than once per week	D or S
509	ISO 7	First Stage Gowning	Total Particulate / Air Viable / Surface Viable	Not less than twice per week	D or S
510	ISO 6	Second Stage Gowning	Total Particulate / Air Viable / Surface Viable	Not less than twice per week	D or S
511/511L ¹	ISO 6 / ISO 5	Sterile Staging	Total Particulate / Air Viable / Surface Viable	Not less than twice per week	D or S
512/512T	ISO 6 / ISO 5	Sterile Filtration 1	Total Particulate / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
513/513T	ISO 6 / ISO 5	Sterile Filtration 2	Total Particulate / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
514	ISO 6	Equipment Exit	Total Particulate / Air Viable / Surface Viable	Not less than twice per week	D or S
515/515T	ISO 6 / ISO 5	Filling Suite 1	Total Particulate / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
516/516T	ISO 6 / ISO 5	Filling Suite 2	Total Particulate / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
517/517T	ISO 6 / ISO 5	Filling Suite 3	Total Particulate / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
518/519	ISO 6 / ISO 7	Personnel Exit 1 / Personnel Exit 2	Total Particulate / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
523/524	ISO 7	Anteroom / Formulation 1	Total Particulate / Air Viable / Surface Viable	Not less than twice per week	D or S
525/526	ISO 7	Anteroom / Formulation 2	Total Particulate / Air Viable / Surface Viable	When in use and not less than twice per week	D or S
527 C/D ²	ISO 7 / ISO 6	Anteroom / Debagging Room	Total Particulate / Air Viable / Surface Viable	When in use and not less than twice per week	D or S

ISO 5 is equivalent to USP, Class 100

ISO 7 is equivalent to USP, Class 10,000

ISO 6 is equivalent to USP, Class 1,000

ISO 8 is equivalent to USP, Class 100,000

*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.

¹ 511L is ISO 5 for air samples and ISO 6 for surfaces.² Inside the Debagging Machine in 527D (527DL) is ISO 6.

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ATTACHMENT 2
ALERT AND ACTION LEVELS

Alert and Action Levels (Static or Dynamic)

Sampling Method		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
Personnel (CFU/25 cm ²)	Air Viables (CFU/m ³)	NA	≥ 1	2	5	5	10	12	25
	Surface Viables	NA	≥ 1	2	3	3	5	25	50
	Floor	2	3	2	3	7	10	25	50
	Total Particulates	N/A	500 particles/m ³	N/A	3000 particles/m ³	N/A	1000 particles/ft ³	N/A	1000 particles/ft ³
Dynamic	0.5 µm	N/A	20 particles/m ³	N/A	29 particles/m ³	N/A	80 particles/ft ³	N/A	100 particles/ft ³
	Total Particulates	100 particles/m ³	500 particles/m ³	1000 particles/m ³	3000 particles/m ³	500 particles/ft ³	1000 particles/ft ³	500 particles/ft ³	1000 particles/ft ³
	0.5 µm	10 particles/m ³	20 particles/m ³	500 particles/m ³	1000 particles/m ³	50 particles/ft ³	80 particles/ft ³	50 particles/ft ³	100 particles/ft ³
	Total Particulates	N/A	≥ 1	N/A	≥ 1	N/A	≥ 1	N/A	≥ 1
Static	Fingertips	N/A	≥ 1	N/A	≥ 1	N/A	≥ 1	N/A	≥ 1
	Head/Arms	> 2	> 3	> 2	> 3	> 2	> 3	> 2	> 3
	Body	> 3	> 5	> 3	> 5	> 3	> 5	> 3	> 5
	Total	N/A	> 11	N/A	> 11	N/A	> 11	N/A	> 11

NOTE: Alert and action levels are met when results exceed the above listed levels.

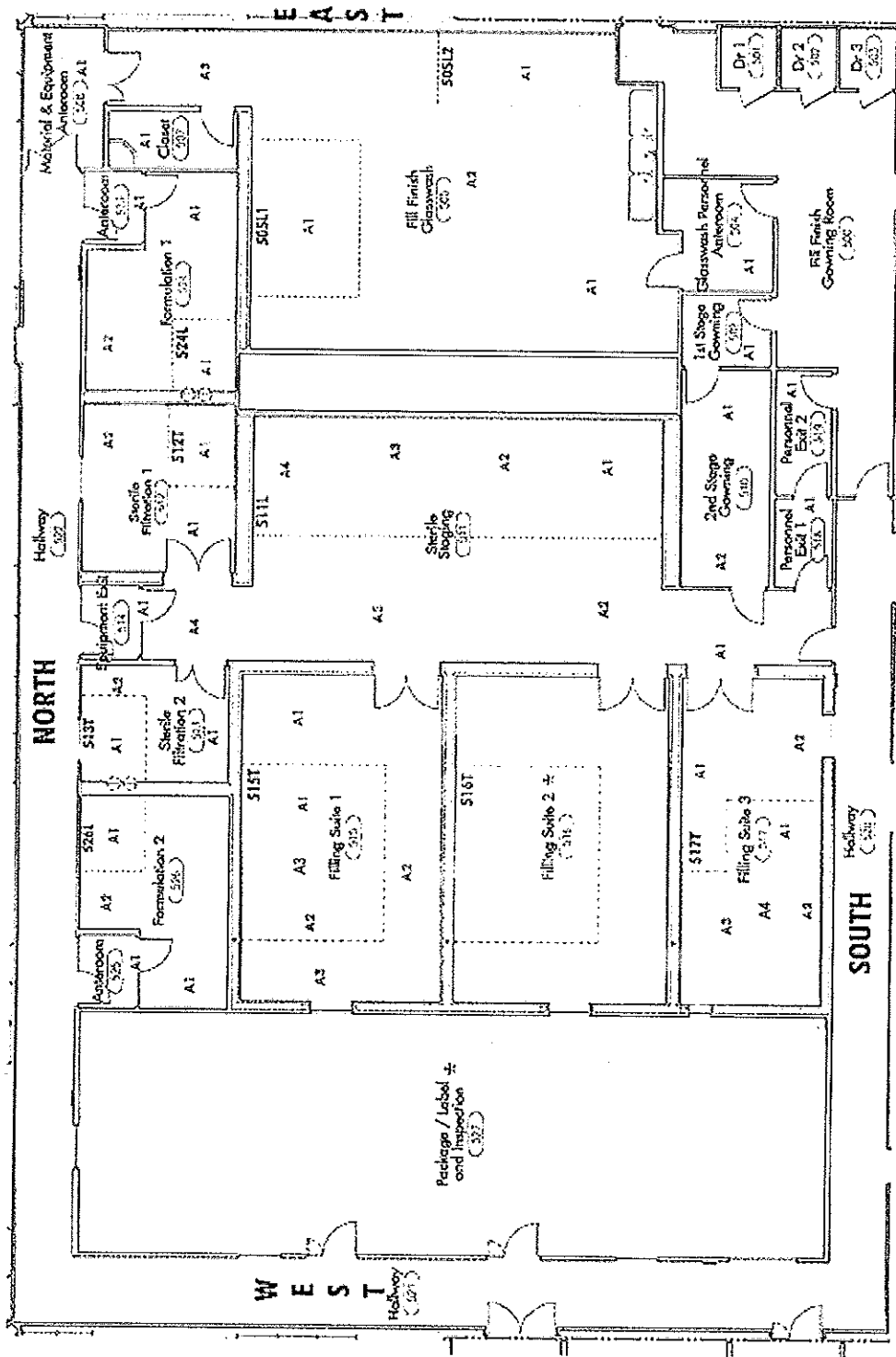
BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

ATTACHMENT 3 TOTAL PARTICULATE AND AIR VIABLE SAMPLE SITES DESCRIPTION OF SITES (Page 1 of 4)

Room	Site ID	Description	Room	Site ID	Description
504	A1	Center Room	515T	A3	Inside Filler
505	A1	By Door to 504	516	A1	East Side of Room
505	A2	Center Room	516	A2	South Side of Room
505	A3	By Door to 507/508	516	A3	West Side of Room
505L1	A1	Center L1	516T	A1	South Side of Tent
505L2	A1	Center L2	516T	A2	North Side of Tent
507	A1	Center Room	516T	A3	By Infeed from 527D
508	A1	Center Room	516T	A4	Inside Syringe Line: <i>- Needle</i> Quadrant IV
509	A1	Center Room	516T	A5	Inside Syringe Line: <i>- Robot Arm</i> Quadrant I
510	A1	Center Room Zone 2	516T	A6	Inside Syringe Line: <i>Stopper bowl</i> Quadrant II
510	A2	Center Room Zone 3	517	A1	North Side of Room
511	A1	By Door to 517	517	A2	South Side of Room
511	A2	By Door to 516	517T	A1	By Door to Fill Setup
511	A3	By Door to 515	517T	A2	By Door to Vial Exit/Entry
511	A4	By Door to 512/513/514	517T	A3	By Door to Stopper/Seal Bowls
511L	A1	By Door to Oven	517T	A4	Inside Filler
511L	A2	By Door to Autoclave ALT-32120	518	A1	Center Room
511L	A3	In Between Autoclaves	519	A1	Center Room
511L	A4	By Door to Autoclave ALT-32121	523	A1	Center Room
512	A1	By Door to 511	524	A1	By Door to 523
512	A2	East Side of Room	524	A2	North Side of Room
512T	A1	Center Tent	524L	A1	Center L
513	A1	By Door to 511	525	A1	Center Room
513	A2	North Side of Room	526	A1	By Door to 525
513T	A1	Center Tent	526	A2	North Side of Room
514	A1	Center Room	526L	A1	Center L
515	A1	Northeast Side of Room	527C	A1	Center Room
515	A2	South Side of Room	527D	A1	North Side of Room
515	A3	By Conveyor	527D	A2	South Side of Room
515T	A1	By Door to Stopper/Seal Bowls	527DL	A1	Inside Debagger
515T	A2	By Door to Vial Exit/Conveyor			

BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

ATTACHMENT 3
TOTAL PARTICULATE AND AIR VIABLE SAMPLE SITES MAP
(Page 2 of 4)

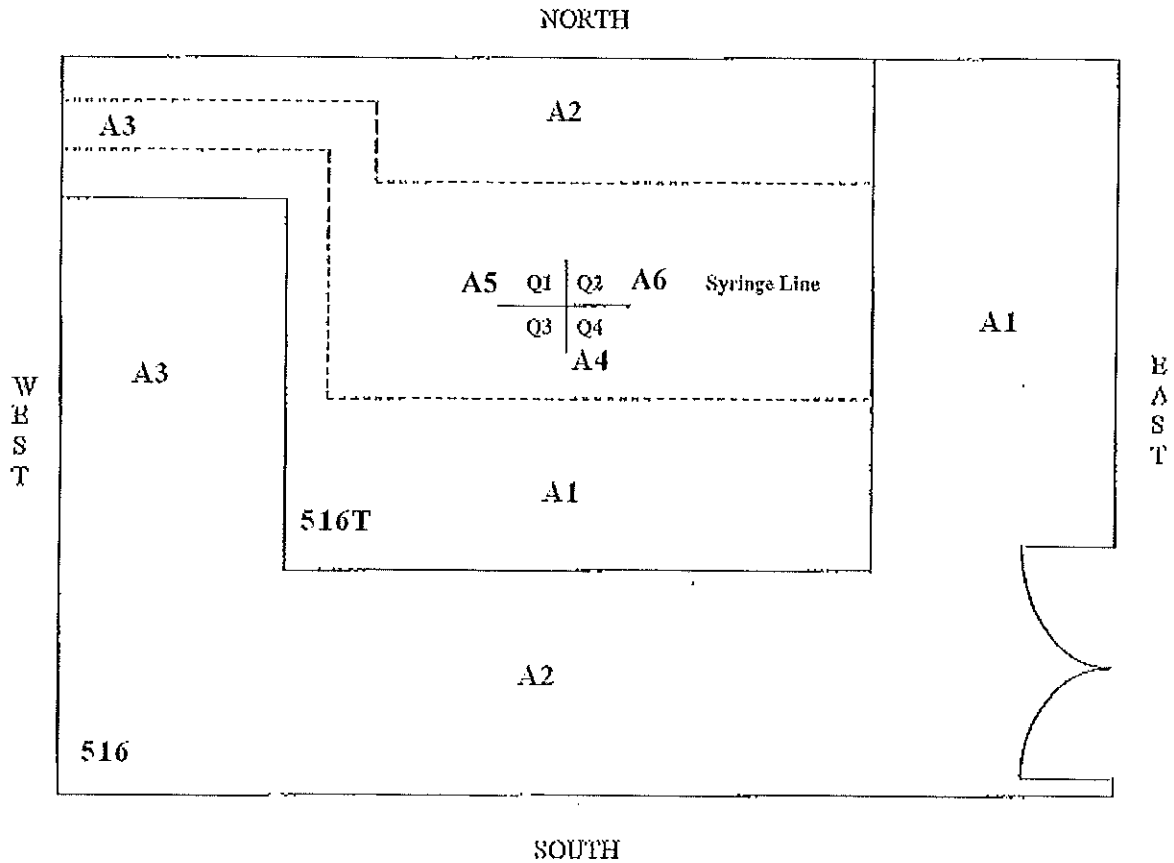


* See Pages 3 and 4 of Attachment 3 for sampling sites of Rooms 516 and 527 C/D

BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

**ATTACHMENT 3
TOTAL PARTICULATE AND AIR VIABLE SAMPLE SITES MAP
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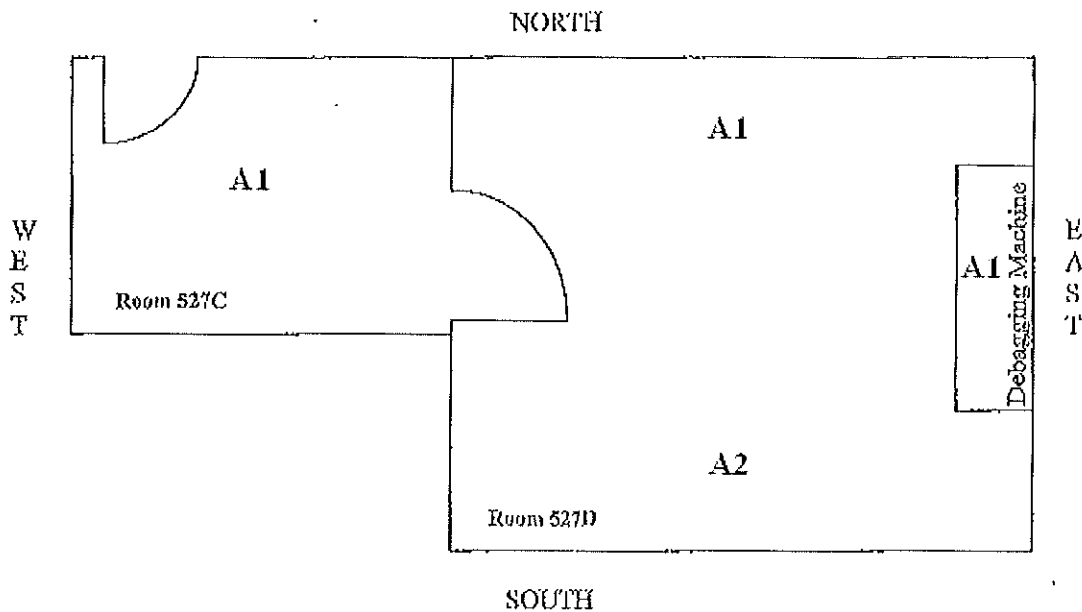
Room 516



BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

**ATTACHMENT 3
TOTAL PARTICULATE AND AIR VIABLE SAMPLE SITES MAP
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Rooms 527 C/D



BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

ATTACHMENT 4
SURFACE VIABLE SAMPLE SITES
DESCRIPTION OF SITES

(Page 1 of 6)

Room	Site ID	Description	Room	Site ID	Description
504	S1	Wall	511	S2	Door Handle to 510
504	S2	Cart/Rack	511	S3	Door Handle to 517
504	S3	Cart/Rack	511	S4	CPMS Station
504	S4	Door Handle to 505	511	S5	Door Handle to 516
504	F1	Floor Center	511	S6	Door Handle to 515
505	S1	Wall Above Sink	511	S7	Door Handle to 513
505	S2	Sink Countertop	511	S8	Door Handle to 514
505	S3	Oven Control Panel	511	S9	Door Handle to 512
505	S4	Autoclave ALT-32120 Control Panel	511	S10	Cart/Rack
505	S5	Autoclave ALT-32121 Control Panel	511	F1	Floor by Door to 517/516
505	S6	Cart/Rack/Table	511	F2	Floor by Door to 515
505	S7	Vial Washer	511	F3	Floor by Door to 512/513/514
505	F1	Floor by Sink	511L	S1	Cart/Rack by Autoclave ALT-32121
505	F2	Floor by Vial Washer	511L	S2	Cart/Rack by Oven
505	F3	Floor by Door to 507/508	511L	S3	Front of Autoclave ALT-32121
505L1	S1	Table	511L	S4	Front of Autoclave ALT-32120
505L1	S2	Cart/Rack	511L	S5	Front of Oven
505L1	S3	Curtain	511L	F1	Floor by Autoclave ALT-32121
505L1	F1	Floor Center	511L	F2	Floor by Oven
505L2	S1	Stopper Washer	512	S1	Door Handle to 511
505L2	S2	Stopper Washer Control Panel	512	S2	Window
505L2	S3	Curtain	512	S3	Curtain
505L2	F1	Floor Center	512	S4	Phone
507	S1	Wall	512	F1	Floor Scale
507	S2	Door Handle to 505	512	F2	Floor by Door to 511
507	S3	Cart/Rack	512T	S1	Window
507	F1	Floor Center	512T	S2	Wall by Portal
507	F2	Floor by Drain	512T	S3	Curtain
508	S1	Wall	512T	S4	Table/Cart/Rack
508	S2	Door Handle to 505	512T	F1	Floor Center
508	S3	Cart/Rack	513	S1	Door Handle to 511
508	S4	Cart/Rack	513	S2	Control Panel
508	F1	Floor Center	513	S3	Curtain
509	S1	Wall	513	S4	Phone
509	S2	Cart/Rack	513	F1	Floor Scale
509	S3	Cart/Rack	513	F2	Floor by Door to 511
509	S4	Door Handle to 510	513T	S1	Window to 526
509	F1	Floor Center	513T	S2	Wall by Portal
510	S1	Cart/Rack Zone 2	513T	S3	Table/Cart/Rack
510	S2	Cart/Rack Zone 3	513T	S4	Curtain
510	S3	Wall	513T	F1	Floor Center
510	S4	Bench	514	S1	Wall
510	S5	Door Handle to 511	514	S2	Wall
510	F1	Floor Zone 2	514	S3	Door to 522
510	F2	Floor Zone 3	514	S4	Door Handle to 511
511	S1	Door Handle to 518	514	F1	Floor Center

BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

**ATTACHMENT 4
SURFACE VIABLE SAMPLE SITES
DESCRIPTION OF SITES**

(Page 2 of 6)

Room	Site ID	Description	Room	Site ID	Description
515	S1	Door Handle to 511	516T	S7	Middle Door Q3
515	S2	Wall	516T	S8	East Door Q4
515	S3	Cart/Rack	516T	S9	Door to Stopper Feed Area
515	S4	Phone	516T	S10	East Door Q2
515	S5	Table	516T	S11	Middle Door Q2
515	S6	Window	516T	S12	West Door Q1
515	S7	West Curtain	516T	S13	Infeed from 527D
515	S8	West Side of South Curtain	516T	F1	Floor North
515	S9	East Side of South Curtain	516T	F2	Floor South
515	S10	Conveyor Track	517	S1	Door Handle to 511
515	S11	Conveyor Exit to 527	517	S2	Window
515	S12	Chair	517	S3	Phone
515	F1	Floor by Door to 511	517	S4	Cart/Rack/Table
515	F2	Floor by Tent Vial Entry	517	S5	Curtain
515	F3	Floor by Tent Vial Exit	517	S6	Chair
515T	S1	West Curtain	517	F1	Floor by Door to 511
515T	S2	West Side of South Curtain	517	F2	Floor by Curtain
515T	S3	East Side of South Curtain	517T	S1	Curtain
515T	S4	Big Portal	517T	S2	Cart/Rack/Table
515T	S5	Small Portal	517T	S3	Pump Cart
515T	S6	Rack/Cart	517T	S4	Door to Stopper/Seal Bowls
515T	S7	Rack/Cart	517T	S5	Door to Filling Setup
515T	S8	Door to Stopper Bowl	517T	S6	Door to Vial Entry
515T	S9	Door to Seal Bowl	517T	S7	Door to Vial Exit
515T	S10	Door to Vial Entry	517T	S8	Control Panel
515T	S11	Control Panel	517T	S9	Conveyor By Vial Exit
515T	S12	Door to Vial Exit	517T	S10	Conveyor Middle
515T	S13	Vial Exit	517T	S11	Conveyor By Suite Exit
515T	S14	Conveyor before Curtain	517T	F1	Floor by Vial Entry/Exit
515T	F1	Floor by Vial Entry	517T	F2	Floor by Stopper/Seal Bowls
515T	F2	Floor by Vial Exit/Conveyor	517T	F3	Floor by Tent Entry / Exit
515T	F3	Floor by Stopper/Seal Bowls	518	S1	Wall
516	S1	Door Handle to 511	518	S2	Wall
516	S2	Wall	518	S3	Door Handle to 519
516	S3	Phone	518	S4	Door to 511
516	S4	West Curtain	518	F1	Floor Center
516	S5	South Curtain	519	S1	Wall
516	S6	Window	519	S2	Wall
516	S7	Rack	519	S3	Door Handle to Room 500
516	S8	Chair	519	S4	Door to 518
516	F1	Floor by Door to 511	519	F1	Floor Center
516	F2	West Floor	523	S1	Wall
516T	S1	West Curtain	523	S2	Door Handle to 524
516T	S2	North Wall	523	S3	Window to 524
516T	S3	Control Panel	523	S4	Cart/Rack
516T	S4	South Curtain	523	F1	Floor Center
516T	S5	Outside of Syringe Line	524	S1	Door Handle to 523
516T	S6	West Door Q3	524	S2	Wall by WFI Drop

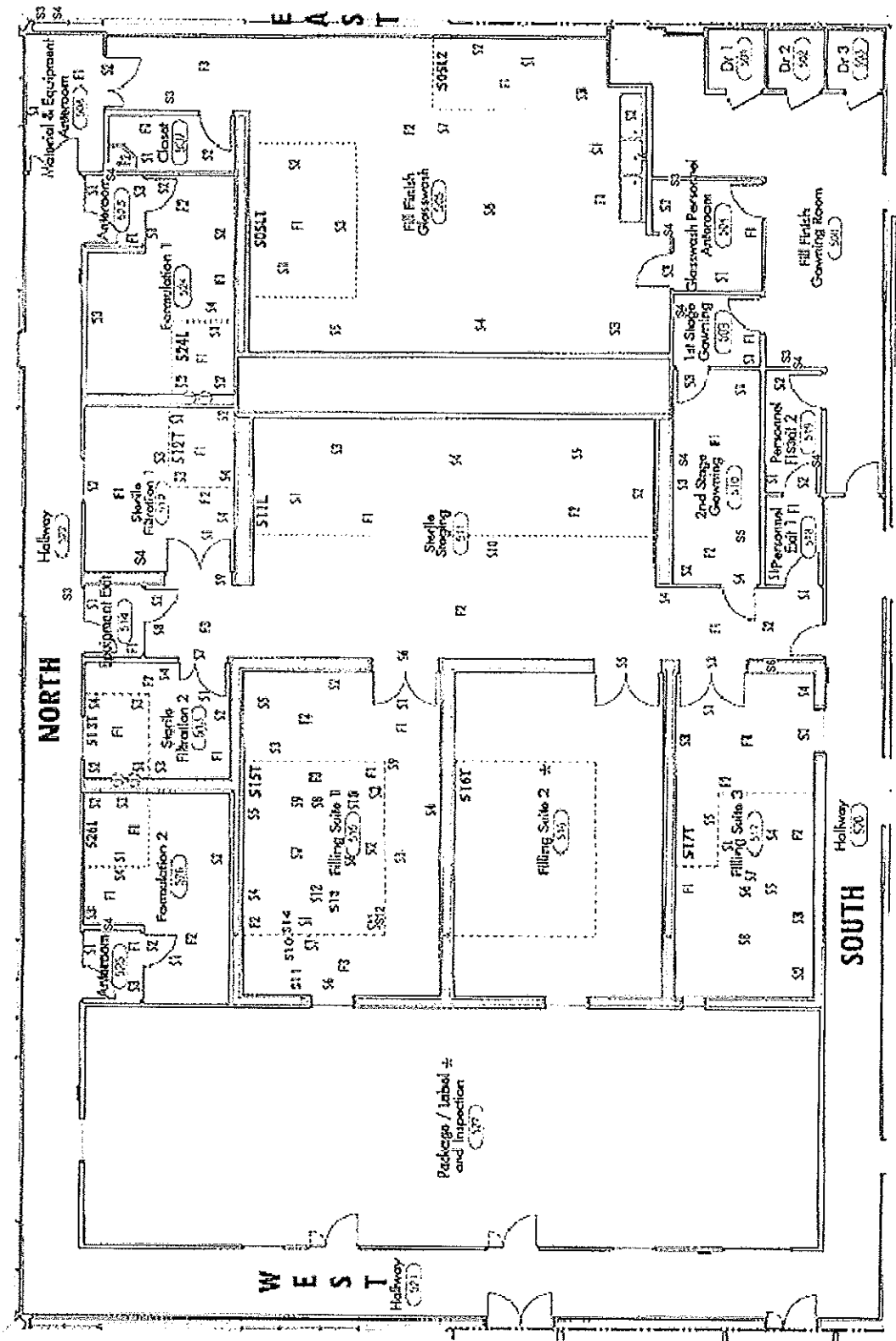
BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

ATTACHMENT 4
SURFACE VIABLE SAMPLE SITES
DESCRIPTION OF SITES
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Room	Site ID	Description
524	S3	Wall by Window
524	S4	Curtain
524	F1	Floor Scale
524	F2	Floor by Door to 523
524L	S1	Curtain
524L	S2	Wall by Portal
524L	S3	Window
524L	F1	Floor Center
525	S1	Wall
525	S2	Door Handle to 526
525	S3	Window to 526
525	S4	Cart/Rack
525	F1	Floor Center
526	S1	Door Handle to 525
526	S2	Portal
526	S3	Control Panel
526	S4	Curtain
526	F1	Floor Scale
526	F2	Floor by Door to 525
526L	S1	Curtain
526L	S2	Wall by Portal
526L	S3	Window
526L	F1	Floor Center
527C	S1	Rack
527C	S2	Wall
527C	S3	Window on Door to 527D
527C	S4	Door Handle to 527 D
527C	F1	Floor by Door to 527D
527D	S1	Wall
527D	S2	Rack
527D	S3	Outside of Debagger
527D	S4	Door Handle to 527C
527D	S5	Infeed Tray
527D	S6	Left Operator Glove
527D	S7	Right Operator Glove
527D	F1	Floor by Door to 527C
527D	F2	Floor by Debagger
527DL	S1	Inside Debagger Left
527DL	S2	Inside Debagger Right
527DL	S3	Inside Debbager Back
527DL	S4	Inside Debagger Center
527DL	S5	Inside Left Debagger Glove
527DL	S6	Inside Right Debagger Glove

BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

ATTACHMENT 4
SURFACE VIABLE SAMPLE SITES MAP
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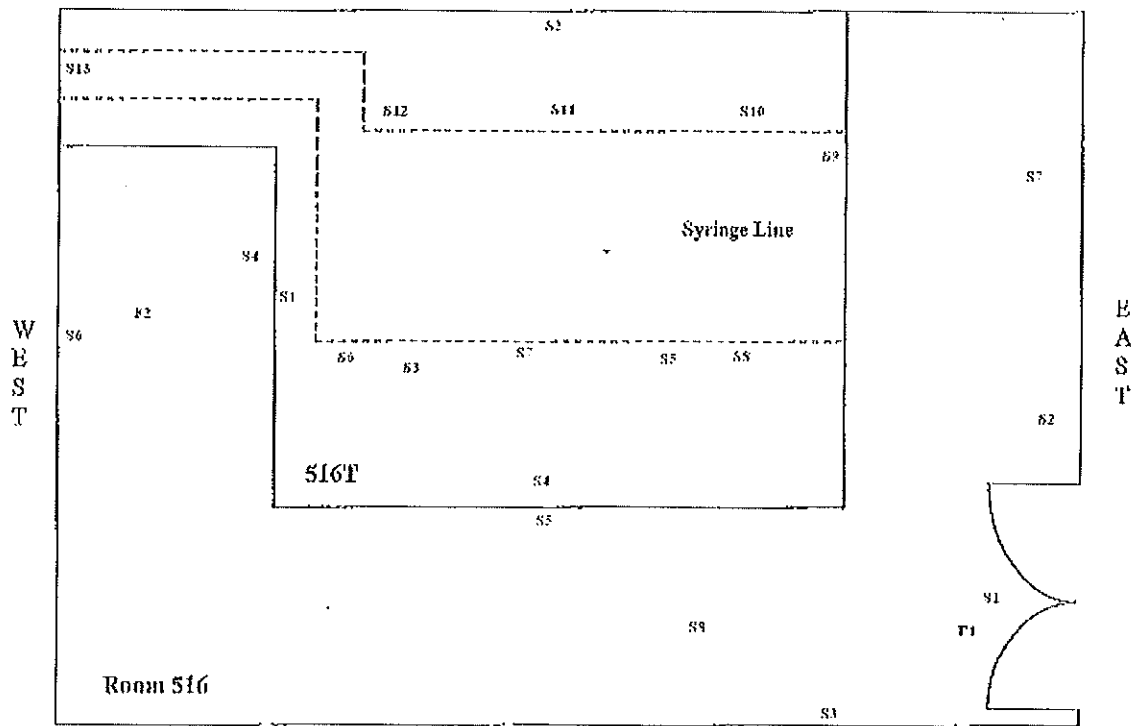
* See Pages 5 and 6 for sampling sites of Rooms 516 and 527 C/D

BUILDING 3 FILL FINISH ENVIRONMENTAL MONITORING

**ATTACHMENT 4
SURFACE VIABLE SAMPLE SITES MAP
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ROOM 516

NORTH



SOUTH

SOP-0544

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**ATTACHMENT 4
SURFACE VIABLE SAMPLE SITES MAP
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ROOMS 527 C/D

