

June 8, 2006

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# OB/GYN- IVF LARORATORY

## *CLEAN ROOM & OR #1*

### *AIR QUALITY- SURVEY REPORT*

→

TO: [REDACTED]  
University of [REDACTED]  
Dept. of Obstetrics & Gynecology [REDACTED]  
Reproductive Testing and In Vitro Fertilization Laboratory  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

FROM: Tom Wheelock  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

SUBJECT: Test Report # [REDACTED]  
Simultaneous Particle/ Microbial Testing of new OB/GYN IVF Lab.  
At-Rest Conditions for Critical Work Zone of HFCB's.  
At-Rest Conditions for Inner Gowning, Main CLRM, OR#1 and hallway.  
Millipore: M AIR T TRYP- SOY AGAR, ATSMTTD60/ F5SN25253  
MFG: 01-DEC-2005 EXP: 01- SEP- 2006

Attached are the results of the Air Quality Survey (AQS), performed in accordance with the ISO #14644-1 International Standard for the new OB/GYN IVF labs. Simultaneous particle & microbial samples were take at all calculated locations.

<u>Simultaneous Sample Locations:</u>	<u>( June 2006 design)</u>
Critical Work Zone: (2) Baker EG 4252's	locations 1-2
Critical Work Zone: Baker EG 6320	locations 3-4
Main IVF CLRM:	locations 5-6
OR #1:	locations 7-8
Hallway:	locations 9-10
Inner Gowning Room:	locations 11-12

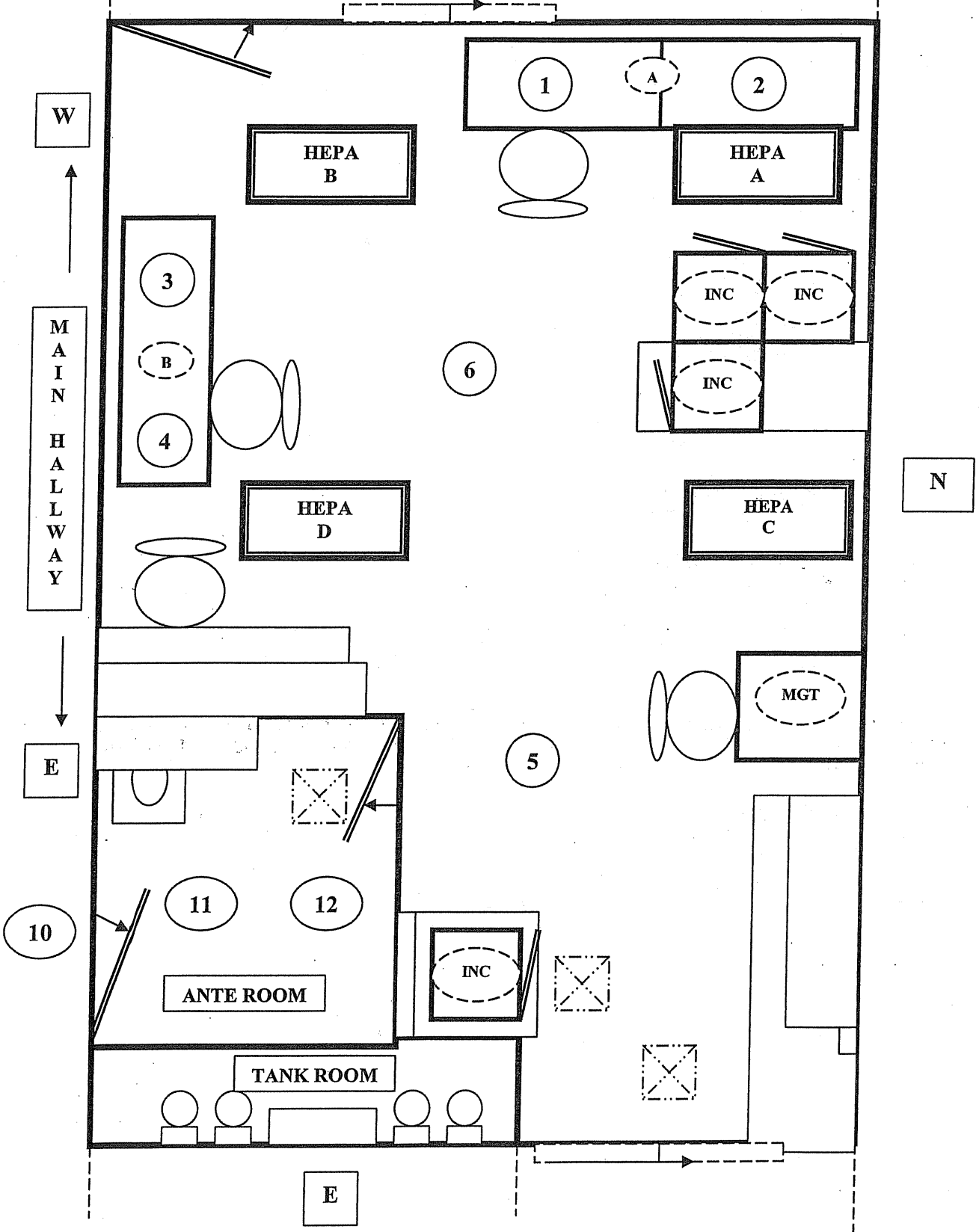
Please contact me with any questions at [REDACTED] or page me at [REDACTED]

# AIR QUALITY SURVEY

## OB/GYN- IVF LAB

JUNE 8, 2006

OR  
#1



DATA: OB/GYN LAB

Baker (A) EG 4252-L/ E-45558-L

Baker (A) EG 4252-R/ E-45559-R

At-Rest Conditions

Clean Room Locations #01-02

Sample Volume: 1.00 CFM

ISO Class #5: @ (0.5 µm)

Date: 06-08-06

Locations	Number of Samples	Particle Counts 0.5 Micron	Notes
01	5	1,391.4/ 77.7	C/L CWZ
02	5	692.2 / 21.2	"

Mean of Averages = 1,041.8/ 49.4

95% ULC = 3,244.4/227.4

Limit for Class #5 (at 0.5 µm) = <3,520.0 particles/ m<sup>3</sup>

The locations described above PASSED the ISO 14644-1&2 International Standard.

DATA: OB/GYN LAB

Baker (B) EG6320/ E-29551

At-Rest Conditions

Clean Room Locations #03-04

Sample Volume: 1.00 CFM

ISO Class #5: @ (0.5 µm)

Date: 06-08-06

Locations	Number of Samples	Particle Counts 0.5 Micron	Notes
03	5	621.5/ 7.1	C/L CWZ
04	5	374.3/ 7.1	"

Mean of Averages = 497.9/ 7.1

95% ULC = 1,276.6/ 7.1

Limit for Class #5(at 0.5 µm) = <3,520.0 particles/ m<sup>3</sup>

The Inner Gowning Room described above PASSED the ISO 14644-1&2 International Standard.

**DATA: OB/GYN LAB**  
**MAIN CLRM**  
**At-Rest Conditions**  
**Clean Room Locations #05- 06**  
**Sample Volume: 1.00 CFM**  
**ISO Class #6: @ (0.5 µm)**  
**Date: 06-08-06**

Locations	Number of Samples	Particle Counts 0.5 Micron CONC/CM	Notes
05	5	11,569.1/ <b>2,366.1</b>	48" above floor
06	5	22,236.5/ <b>332.0</b>	"

Mean of Averages = 10,940.0/ 1,349.0

**95% ULC = 18,689.9/ 7,756.5**

**Limit for Class #6 (at 0.5 µm) = <35,200.0 particles/ m<sup>3</sup>**

The OB/GYN CLRM described above **PASSED** the ISO 14644-1&2 International Standard.

**DFHM- A: 000 CFM                      SYSTEM'S MANAGEMENT**

**DFHM- B: 000 CFM**

**DFHM- C: 000 CFM**

**DFHM- D: 000 CFM**

**ROOM AIR CHANGES PER HOUR:**

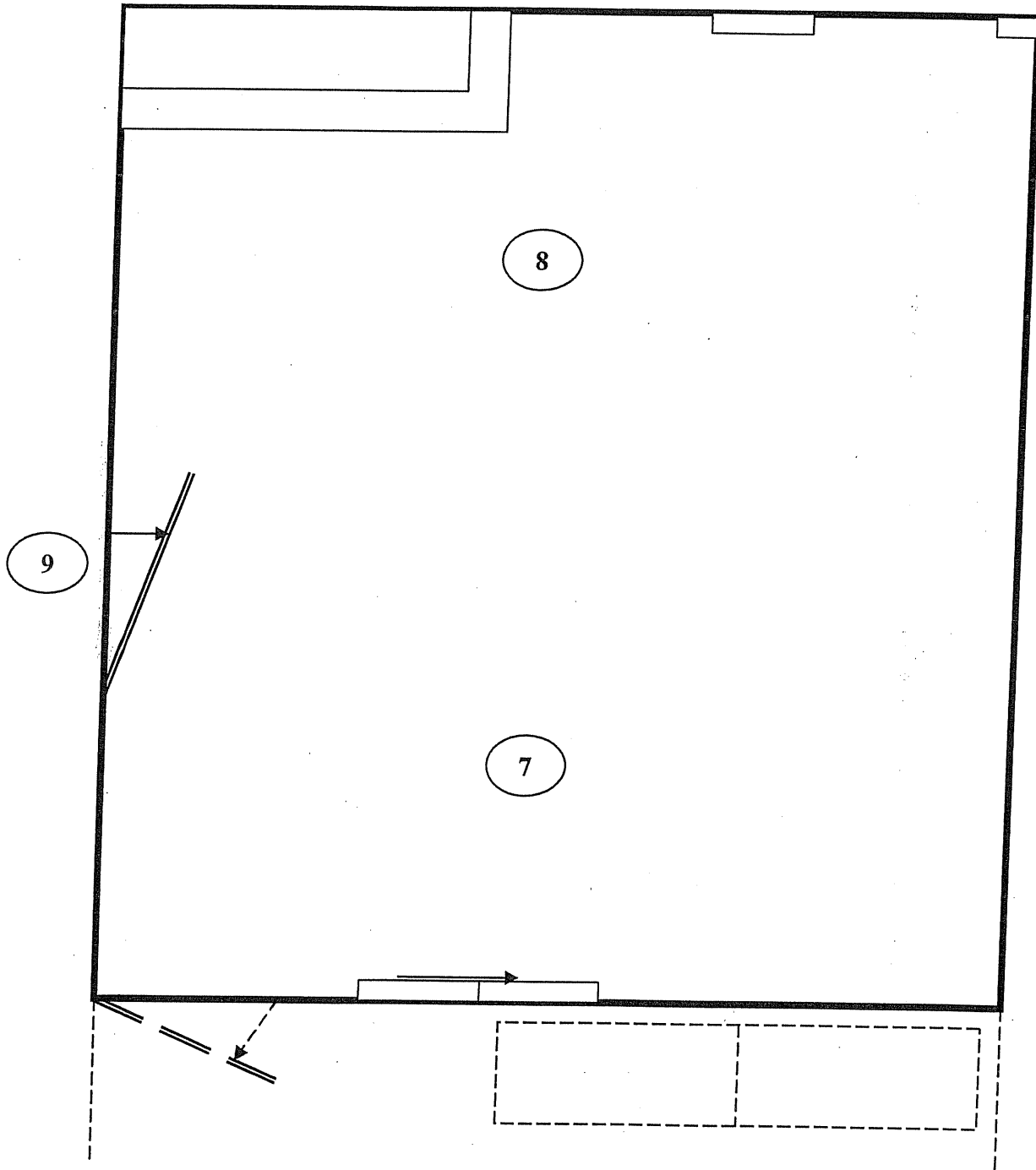
**MAIN IVF CLRM CUBIC FEET DIMENSIONS: 2,822 FT<sup>3</sup>**

**CALCULATION: 0000 CFM X 60 = 000000 / 2,822 = 00 A CH PER HR.**

# AIR QUALITY SURVEY

## OB/GYN- OR #1

June 8, 2006



**DATA: OB/GYN LAB**  
**MAIN OR #1- CLRM**  
**At-Rest Conditions**  
**Clean Room Locations #7- 8**  
**Sample Volume: 1.00 CFM**  
**ISO Class #7: @ (0.5 µm)**  
**Date: 06-08-06**

Locations	Number of Samples	Particle Counts 0.5 Micron CONC/CM	Notes
7	5	337,160.9/ 165,484.5	48" above floor
8	5	249,121.4/ 153,887.2	"

Mean of Averages = 258,037.2/ 159,685.9

**95% ULC = 300,410.0/ 196, 217.5**

**Limit for Class #6 (at 0.5 µm) = <352,000.0 particles/ m<sup>3</sup>**

The OB/GYN OR #1- CLRM described above **PASSED** the ISO 14644-1&2 International Standard.

**DATA: OB/GYN LAB**  
**MAIN HALLWAY**  
**At-Rest Conditions**  
**Clean Room Locations #9- 10**  
**Sample Volume: 1.00 CFM**  
**ISO Class #8: @ (0.5 µm)**  
**Date: 06-08-06**

Locations	Number of Samples	Particle Counts 0.5 Micron	Notes
9	5	1,614,245.0/334,401.6	48" above floor
10	5	1,304,842.0/ 373,078.3	"

Mean of Averages = 1,459,543.0/ 353,740.0

**95% ULC = 2,434,165.0/475,571.3**

**Limit for Class #8 (at 0.5 µm) = <3,520,000.0 particles/ m<sup>3</sup>**

The MAIN CLRM HALLWAY described above **PASSED** the ISO 14644-1&2 International Standard.

**DATA: OB/GYN LAB**  
**MAIN CLRM ANTE ROOM**  
**At-Rest Conditions**  
**Clean Room Locations #11-12**  
**Sample Volume: 1.00 CFM**  
**ISO Class #7: @ (0.5 µm)**  
**Date: 06-08-06**

Locations	Number of Samples	Particle Counts 0.5 Micron	Notes
11	5	247,614.7/53,614.7	48" above floor
12	5	203,518.4/ 50,302.2	"

Mean of Averages = 225,566.5/ 51,958.5

**95% ULC** = 364,469.7/ **62,392.9**

**Limit for Class #7 (at 0.5 µm) = <352,000.0 particles/ m<sup>3</sup>**

The Inner Gowning Room described above **PASSED** the ISO 14644-1&2 International Standard.

**OB/GYN- IVF LABORATORY**  
**PRINT-OUTS**

**ISO 14644-1 REPORT**

ISO CLASS 5 (AT 0.5 uM)  
06/08/06 13:38:58  
START 06/08/06 13:27:13  
END 06/08/06 13:38:08

SAMPLE VOLUME = 1.0CF  
SIZE = >0.5uM      AVERAGE      AVERAGE  
ID                    #SAMPLES    COUNTS      CONC/CM  
1-A-HFCB            5            2.2          77.7  
2                      5            8.600       21.2

MEAN OF AVERAGES =      49.4  
STANDARD DEVIATION =    48.8  
STANDARD ERROR =        28.3  
95% UCL =                227.4

PASS

**ISO 14644-1 REPORT**

ISO CLASS 6 (AT 0.5 uM)  
06/08/06 14:05:58  
START 06/08/06 13:54:18  
END 06/08/06 14:05:22

SAMPLE VOLUME = 1.0CF  
SIZE = >0.5uM      AVERAGE      AVERAGE  
ID                    #SAMPLES    COUNTS      CONC/CM  
5-IVF LAB            5            67.8        2366.1  
6                      5            9.4          332.0

MEAN OF AVERAGES =      1349.8  
STANDARD DEVIATION =    1438.3  
STANDARD ERROR =        1817.1  
95% UCL =                7756.5

PASS

**ISO 14644-1 REPORT**

ISO CLASS 8 (AT 0.5 uM)  
06/08/06 14:41:58  
START 06/08/06 14:29:45  
END 06/08/06 14:41:00

SAMPLE VOLUME = 1.0CF  
SIZE = >0.5uM      AVERAGE      AVERAGE  
ID                    #SAMPLES    COUNTS      CONC/CM  
9-MCORR              5            9469.2      334401.6  
18                     5            10564.4     373078.3

MEAN OF AVERAGES =      353740.8  
STANDARD DEVIATION =    27348.5  
STANDARD ERROR =        19338.3  
95% UCL =                475571.3

PASS

**ISO 14644-1 REPORT**

ISO CLASS 5 (AT 0.5 uM)  
06/08/06 13:51:44  
START 06/08/06 13:40:48  
END 06/08/06 13:51:25

SAMPLE VOLUME = 1.0CF  
SIZE = >0.5uM      AVERAGE      AVERAGE  
ID                    #SAMPLES    COUNTS      CONC/CM  
3-B-HFCB            5            0.200       7.1  
4                      5            0.200       7.1

MEAN OF AVERAGES =      7.1  
STANDARD DEVIATION =    8  
STANDARD ERROR =        8  
95% UCL =                7.1

PASS

**ISO 14644-1 REPORT**

ISO CLASS 7 (AT 0.5 uM)  
06/08/06 14:24:20  
START 06/08/06 14:00:32  
END 06/08/06 14:21:52

SAMPLE VOLUME = 1.0CF  
SIZE = >0.5uM      AVERAGE      AVERAGE  
ID                    #SAMPLES    COUNTS      CONC/CM  
7-ORR1               5            4686.0      165484.5  
8                      5            4357.6      153887.2

MEAN OF AVERAGES =      159685.9  
STANDARD DEVIATION =    8200.6  
STANDARD ERROR =        5798.7  
95% UCL =                196217.5

PASS

**ISO 14644-1 REPORT**

ISO CLASS 7 (AT 0.5 uM)  
06/08/06 15:01:10  
START 06/08/06 14:47:34  
END 06/08/06 14:59:33

SAMPLE VOLUME = 1.0CF  
SIZE = >0.5uM      AVERAGE      AVERAGE  
ID                    #SAMPLES    COUNTS      CONC/CM  
11-AR                5            1510.2      53614.7  
12                     5            1424.4      50302.2

MEAN OF AVERAGES =      51958.5  
STANDARD DEVIATION =    2342.3  
STANDARD ERROR =        1656.3  
95% UCL =                62392.9

PASS