

## **IMPORTANT**

New screen: **Maternal Integrated Screen.**

\*\*\*\* A “test results” table and Sample Reports are **provided below** \*\*\*\*

The **Maternal Integrated Screen** requires two separate specimens:

- The First Sample is a serum collected and submitted to the laboratory in the **first** trimester
- The Second Sample is a serum collected and submitted to the laboratory in the **second** trimester

The **Maternal Integrated Screen** report is generated in the second trimester after the second specimen has been tested. Information is used from both specimens and “integrated” into a single screen which provides better risk assessment than can be achieved using only the information from either the first or second trimester alone.

Although a screen result is not reported in the first trimester for the First Sample of the **Maternal Integrated Screen**, a pseudo-report is generated. The **Sample 1 Maternal Integrated Screen** report allows the lab to:

- Indicate to the submitter that the First Sample has been received
- Present patient and specimen information submitted with the specimen for their review
- Specify the appropriate date range for collection of the Second Sample

Sample text from a **Sample 1 Maternal Integrated Screen** report:

*A Stage One (first trimester) sample for the Iowa Integrated Screen has been received with the above clinical information. Please review this information and call 319-356-3561 with questions or corrections. Missing or incorrect data will result in inaccurate interpretation.*

*A Stage Two (second trimester) sample should be collected between 2009-01-03 and 2009-02-13. The results of the Iowa Integrated Screen will be reported after the second sample has been received.*

## Maternal Integrated Screen

Marker	Laboratory Result
NT (optional) PAPP-A AFP uE3 hCG Inhibin	MoM

Specimen information on two samples:	Lab Number Collect Date Date Received Maternal Weight Gestational Age
--------------------------------------	---

Screen	Screen Cut-off	Laboratory Result	Interpretation	Recommended Action
(Open) Neural Tube Defects NTD	AFP MoM $\geq 2.2$	AFP MoM	Screen Negative for NTD	No further action
			Screen Positive for NTD	Level II Ultrasound and/or consideration for amniocentesis
Age Related DS Risk	N/A	Risk [1:n]	N/A	N/A
Down Syndrome (DS) Risk	1:150	Risk [1:n]	Screen Negative for Downs	No further action
			Screen Positive for Downs	Level II ultrasound, counseling and consideration for diagnostic testing
Trisomy 18 Risk	1:100	Risk [1:n]	Screen Negative for Trisomy 18	No further action
			Screen Positive for Trisomy 18	Level II ultrasound, counseling and consideration for diagnostic testing

If <b>ALL</b> screens are negative	Screen Negative	No further action
If <b>ANY</b> screen is positive each will be listed		

### TEST TRAILER

Screening will detect approximately 85% of fetuses with Down syndrome, 80% of fetuses with Trisomy 18 and 85% of fetuses with open neural tube defects in a singleton pregnancy. This test does not reliably detect other chromosomal abnormalities. NT measurement greater than or equal to 3.0 mm increases the risk for aneuploidy, heart defects and other congenital abnormalities. Maternal screening has some level of inherent false negative and false positive results and is not a substitute for diagnostic testing. This report is based on the clinical information provided. Missing or incorrect data will result in an inaccurate interpretation. Please review and call 319-356-3561 with questions. This test uses a kit designated by the manufacturer as, "for research use, not for clinical use." The performance characteristics of this test were validated by the University Hygienic Laboratory. The FDA has not approved or cleared this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. Integrated Test Technology is under license from Intema Ltd, UK.



# Hygienic Laboratory

*The University of Iowa*

AFP-DEPT  
UNIVERSITY OF IOWA HYGIENIC LAB  
102 OAKDALE CAMPUS  
  
IOWA CITY, IA 52242-

<i>Patient</i>	<b>INTEGRATED, FIRST SAMPLE</b>
<i>Lab #</i>	2008333333 <i>Revision 1</i>
<i>Date Collected</i>	12-10-2008
<i>Date Received</i>	12-16-2008
<i>Birth Date</i>	03-02-1973
<i>Gender</i>	F
<i>Address</i>	ia
<i>Phone #</i>	
<i>Patient Id</i>	
<i>Provider</i>	

***There are no further tests pending on this specimen***

### ***Sample 1 Maternal Integrated Screen***

***Corrected Version 1 on 01-13-2009***  
***Analysis performed in Iowa City***

<i>Patient History</i>	<i>Maternal Age At Delivery</i>	36.3 years	<i>Gestational Age</i>	81 days
	<i>Maternal Weight</i>	100.0 lbs.	<i>Ultrasound</i>	2008-12-10
	<i>Maternal Race</i>	White	<i>CRL</i>	48 mm
	<i>Sonographer</i>	Black	<i>NT</i>	0.8 mm

***Laboratory Results*** A Stage One (first trimester) sample for the Iowa Integrated Screen has been received with the above clinical information. Please review this information and call 319-356-3561 with questions or corrections. Missing or incorrect data will result in inaccurate interpretation.

A Stage Two (second trimester) sample should be collected between 2009-01-03 and 2009-02-13. The results of the Iowa Integrated Screen will be reported after the second sample has been received.



# Hygienic Laboratory

*The University of Iowa*

AFP-DEPT  
 UNIVERSITY OF IOWA HYGIENIC LAB  
 102 OAKDALE CAMPUS  
  
 IOWA CITY, IA 52242-

<i>Patient</i>	INTEGRATED, SCREEN NEG
<i>Lab #</i>	2009000036
<i>Date Collected</i>	01-12-2009
<i>Date Received</i>	01-13-2009
<i>Birth Date</i>	03-02-1973
<i>Gender</i>	
<i>Address</i>	ia
<i>Phone #</i>	
<i>Patient Id</i>	
<i>Provider</i>	

***There are no further tests pending on this specimen***

## ***Maternal Integrated Screen***

*Analysis performed in Iowa City*

***Patient History***

<i>Maternal Age At Delivery</i>	36.3 years	<i>Ultrasound</i>	2008-12-10
<i>Maternal Race</i>	White	<i>CRL</i>	48 mm
<i>Number of Fetuses</i>	1	<i>NT</i>	0.8 mm
<i>Insulin Dependent Diabetic</i>	No	<i>Sonographer</i>	Black
<i>Family History of NTD</i>	No		

### **First Trimester**

<i>Lab #</i>	2008333333
<i>Collected</i>	2008-12-10
<i>Received</i>	2008-12-16
<i>Maternal Weight</i>	100.0 lbs.
<i>Gestational Age</i>	81 days

### **Second Trimester**

<i>Lab #</i>	2009000036
<i>Collected</i>	2009-01-12
<i>Received</i>	2009-01-13
<i>Maternal Weight</i>	120.0 lbs.
<i>Gestational Age</i>	114 days

***Laboratory Results***

<u>Testing</u>	<u>MoM</u>	<u>Screening Cutoffs</u>
NT	0.65	
PAPP-A	0.20	
AFP	1.01	NTD >= 2.2
Estriol (uE3)	0.86	
HCG	0.75	
Inhibin	1.05	

<u>Screen</u>	<u>Risk</u>	<u>Screening Cutoffs</u>
Age Related DS Risk	1:220	
Down Syndrome (DS) Risk	1:9500	1:150
Trisomy 18 Risk	1:24000	1:100

<u>Interpretation</u>	<u>Recommended Action</u>
Screen Negative	No further action



# Hygienic Laboratory

*The University of Iowa*

Patient | INTEGRATED, SCREEN NEG  
Lab # | 2009000036

## Note

Screening will detect approximately 85% of fetuses with Down Syndrome, 80% of fetuses with Trisomy 18 and 85% of fetuses with open neural tube defects in a singleton pregnancy. This test does not reliably detect other chromosomal abnormalities. NT measurement greater than or equal to 3.0 mm increases the risk for aneuploidy, heart defects and other congenital abnormalities. Maternal screening has some level of inherent false negative and false positive results and is not a substitute for diagnostic testing. This report is based on the clinical information provided. Missing or incorrect data will result in an inaccurate interpretation. Please review and call 319-356-3561 with questions. This test uses a kit designated by the manufacturer as, "for research use, not for clinical use." The performance characteristics of this test were validated by the University Hygienic Laboratory. The FDA has not approved or cleared this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. Integrated Test Technology is under license from INtema Ltd, UK.



# Hygienic Laboratory

*The University of Iowa*

AFP-DEPT  
 UNIVERSITY OF IOWA HYGIENIC LAB  
 102 OAKDALE CAMPUS  
  
 IOWA CITY, IA 52242-

<i>Patient</i>	INTEGRATED, PP NTD
<i>Lab #</i>	2009000035
<i>Date Collected</i>	01-12-2009
<i>Date Received</i>	01-13-2009
<i>Birth Date</i>	03-02-1973
<i>Gender</i>	
<i>Address</i>	ia
<i>Phone #</i>	
<i>Patient Id</i>	
<i>Provider</i>	

***There are no further tests pending on this specimen***

## ***Maternal Integrated Screen***

*Analysis performed in Iowa City*

***Patient History***

<i>Maternal Age At Delivery</i>	36.3 years	<i>Ultrasound</i>	2008-12-10
<i>Maternal Race</i>	White	<i>CRL</i>	48 mm
<i>Number of Fetuses</i>	1	<i>NT</i>	0.8 mm
<i>Insulin Dependent Diabetic</i>	No	<i>Sonographer</i>	Black
<i>Family History of NTD</i>	No		

**First Trimester**

<i>Lab #</i>	2008333333
<i>Collected</i>	2008-12-10
<i>Received</i>	2008-12-16
<i>Maternal Weight</i>	100.0 lbs.
<i>Gestational Age</i>	81 days

**Second Trimester**

<i>Lab #</i>	2009000035
<i>Collected</i>	2009-01-12
<i>Received</i>	2009-01-13
<i>Maternal Weight</i>	120.0 lbs.
<i>Gestational Age</i>	114 days

***Laboratory Results***

<u>Testing</u>	<u>MoM</u>	<u>Screening Cutoffs</u>
NT	0.65	
PAPP-A	0.20	
AFP	2.45	NTD >= 2.2
Estriol (uE3)	0.86	
HCG	1.02	
Inhibin	1.05	

<u>Screen</u>	<u>Risk</u>	<u>Screening Cutoffs</u>
Age Related DS Risk	1:220	
Down Syndrome (DS) Risk	1:99000	1:150
Trisomy 18 Risk	1:54000	1:100

**Interpretation**

Screen Positive for NTD  
 Screen Negative for Downs  
 Screen Negative for Trisomy 18

**Recommended Action**

Level II Ultrasound and/or consideration for amniocentesis  
 No further action  
 No further action



# Hygienic Laboratory

*The University of Iowa*

Patient | **INTEGRATED, PP NTD**  
Lab # | 2009000035

## Note

*Screening will detect approximately 85% of fetuses with Down Syndrome, 80% of fetuses with Trisomy 18 and 85% of fetuses with open neural tube defects in a singleton pregnancy. This test does not reliably detect other chromosomal abnormalities. NT measurement greater than or equal to 3.0 mm increases the risk for aneuploidy, heart defects and other congenital abnormalities. Maternal screening has some level of inherent false negative and false positive results and is not a substitute for diagnostic testing. This report is based on the clinical information provided. Missing or incorrect data will result in an inaccurate interpretation. Please review and call 319-356-3561 with questions. This test uses a kit designated by the manufacturer as, "for research use, not for clinical use." The performance characteristics of this test were validated by the University Hygienic Laboratory. The FDA has not approved or cleared this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. Integrated Test Technology is under license from INtema Ltd, UK.*



# Hygienic Laboratory

*The University of Iowa*

AFP-DEPT  
 UNIVERSITY OF IOWA HYGIENIC LAB  
 102 OAKDALE CAMPUS  
  
 IOWA CITY, IA 52242-

<i>Patient</i>	<b>INTEGRATED, PP DS</b>
<i>Lab #</i>	2009000033
<i>Date Collected</i>	01-12-2009
<i>Date Received</i>	01-13-2009
<i>Birth Date</i>	03-02-1973
<i>Gender</i>	F
<i>Address</i>	ia
<i>Phone #</i>	
<i>Patient Id</i>	
<i>Provider</i>	

***There are no further tests pending on this specimen***

## ***Maternal Integrated Screen***

*Analysis performed in Iowa City*

***Patient History***

<i>Maternal Age At Delivery</i>	36.3 years	<i>Ultrasound</i>	2008-12-10
<i>Maternal Race</i>	White	<i>CRL</i>	48 mm
<i>Number of Fetuses</i>	1	<i>NT</i>	0.8 mm
<i>Insulin Dependent Diabetic</i>	No	<i>Sonographer</i>	Black
<i>Family History of NTD</i>	No		

**First Trimester**

<i>Lab #</i>	2008333333
<i>Collected</i>	2008-12-10
<i>Received</i>	2008-12-16
<i>Maternal Weight</i>	100.0 lbs.
<i>Gestational Age</i>	81 days

**Second Trimester**

<i>Lab #</i>	2009000033
<i>Collected</i>	2009-01-12
<i>Received</i>	2009-01-13
<i>Maternal Weight</i>	120.0 lbs.
<i>Gestational Age</i>	114 days

***Laboratory Results***

<u>Testing</u>	<u>MoM</u>	<u>Screening Cutoffs</u>
NT	0.65	
PAPP-A	0.20	
AFP	0.44	NTD >= 2.2
Estriol (uE3)	0.59	
HCG	1.05	
Inhibin	1.31	

<u>Screen</u>	<u>Risk</u>	<u>Screening Cutoffs</u>
Age Related DS Risk	1:220	
Down Syndrome (DS) Risk	1:21	1:150
Trisomy 18 Risk	1:2500	1:100

**Interpretation**

Screen Negative for NTD  
 Screen Positive for Downs  
 Screen Negative for Trisomy 18

**Recommended Action**

No further action  
 Level II ultrasound, counseling and consideration for diagnostic testing  
 No further action



# Hygienic Laboratory

*The University of Iowa*

Patient | **INTEGRATED, PP DS**  
Lab # | 2009000033

## Note

Screening will detect approximately 85% of fetuses with Down Syndrome, 80% of fetuses with Trisomy 18 and 85% of fetuses with open neural tube defects in a singleton pregnancy. This test does not reliably detect other chromosomal abnormalities. NT measurement greater than or equal to 3.0 mm increases the risk for aneuploidy, heart defects and other congenital abnormalities. Maternal screening has some level of inherent false negative and false positive results and is not a substitute for diagnostic testing. This report is based on the clinical information provided. Missing or incorrect data will result in an inaccurate interpretation. Please review and call 319-356-3561 with questions. This test uses a kit designated by the manufacturer as, "for research use, not for clinical use." The performance characteristics of this test were validated by the University Hygienic Laboratory. The FDA has not approved or cleared this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. Integrated Test Technology is under license from INtema Ltd, UK.



# Hygienic Laboratory

*The University of Iowa*

AFP-DEPT  
 UNIVERSITY OF IOWA HYGIENIC LAB  
 102 OAKDALE CAMPUS  
  
 IOWA CITY, IA 52242-

*Patient* | **INTEGRATED, PP T18**  
*Lab #* | 2009000034  
*Date Collected* | 01-12-2009  
*Date Received* | 01-13-2009  
*Birth Date* | 03-02-1973  
*Gender* |  
  
*Address* |  
 ia  
  
*Phone #* |  
*Patient Id* |  
*Provider* |

***There are no further tests pending on this specimen***

## ***Maternal Integrated Screen***

*Analysis performed in Iowa City*

***Patient History***

<i>Maternal Age At Delivery</i>	36.3 years	<i>Ultrasound</i>	2008-12-10
<i>Maternal Race</i>	White	<i>CRL</i>	48 mm
<i>Number of Fetuses</i>	1	<i>NT</i>	0.8 mm
<i>Insulin Dependent Diabetic</i>	No	<i>Sonographer</i>	Black
<i>Family History of NTD</i>	No		

**First Trimester**

<i>Lab #</i>	2008333333
<i>Collected</i>	2008-12-10
<i>Received</i>	2008-12-16
<i>Maternal Weight</i>	100.0 lbs.
<i>Gestational Age</i>	81 days

**Second Trimester**

<i>Lab #</i>	2009000034
<i>Collected</i>	2009-01-12
<i>Received</i>	2009-01-13
<i>Maternal Weight</i>	120.0 lbs.
<i>Gestational Age</i>	114 days

***Laboratory Results***

<u>Testing</u>	<u>MoM</u>	<u>Screening Cutoffs</u>
NT	0.65	
PAPP-A	0.20	
AFP	1.01	NTD >= 2.2
Estriol (uE3)	0.32	
HCG	0.60	
Inhibin	1.05	

<u>Screen</u>	<u>Risk</u>	<u>Screening Cutoffs</u>
Age Related DS Risk	1:220	
Down Syndrome (DS) Risk	1:630	1:150
Trisomy 18 Risk	1:68	1:100

<u>Interpretation</u>	<u>Recommended Action</u>
Screen Negative for NTD	No further action
Screen Negative for Downs	No further action
Screen Positive for Trisomy 18	Level II ultrasound, counseling and consideration for diagnostic testing



# Hygienic Laboratory

*The University of Iowa*

Patient | **INTEGRATED, PP T18**

Lab # | 2009000034

## Note

*Screening will detect approximately 85% of fetuses with Down Syndrome, 80% of fetuses with Trisomy 18 and 85% of fetuses with open neural tube defects in a singleton pregnancy. This test does not reliably detect other chromosomal abnormalities. NT measurement greater than or equal to 3.0 mm increases the risk for aneuploidy, heart defects and other congenital abnormalities. Maternal screening has some level of inherent false negative and false positive results and is not a substitute for diagnostic testing. This report is based on the clinical information provided. Missing or incorrect data will result in an inaccurate interpretation. Please review and call 319-356-3561 with questions. This test uses a kit designated by the manufacturer as, "for research use, not for clinical use." The performance characteristics of this test were validated by the University Hygienic Laboratory. The FDA has not approved or cleared this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. Integrated Test Technology is under license from INtema Ltd, UK.*