Utilization of Clinical Laboratory Reports with Graphical Elements

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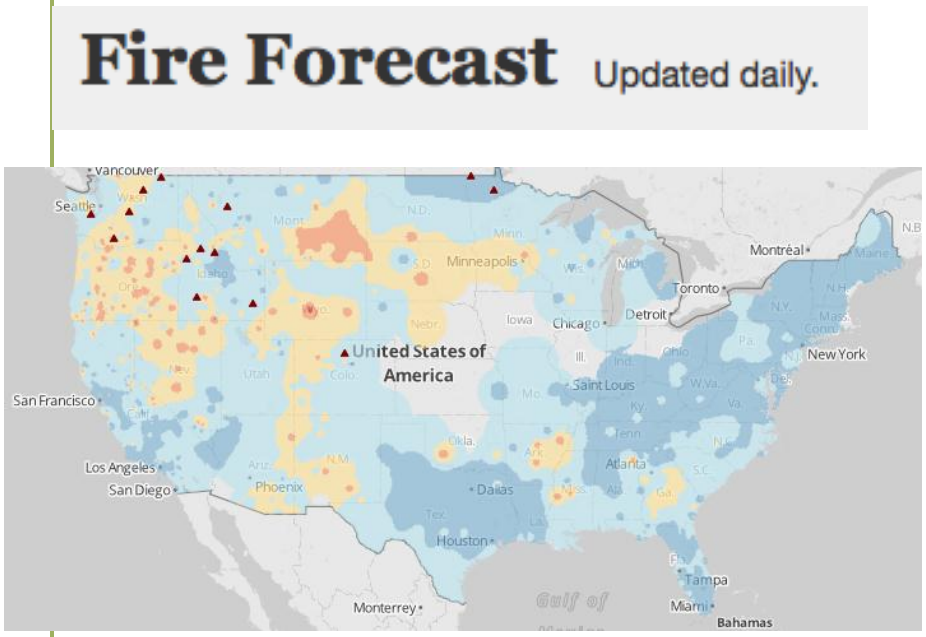
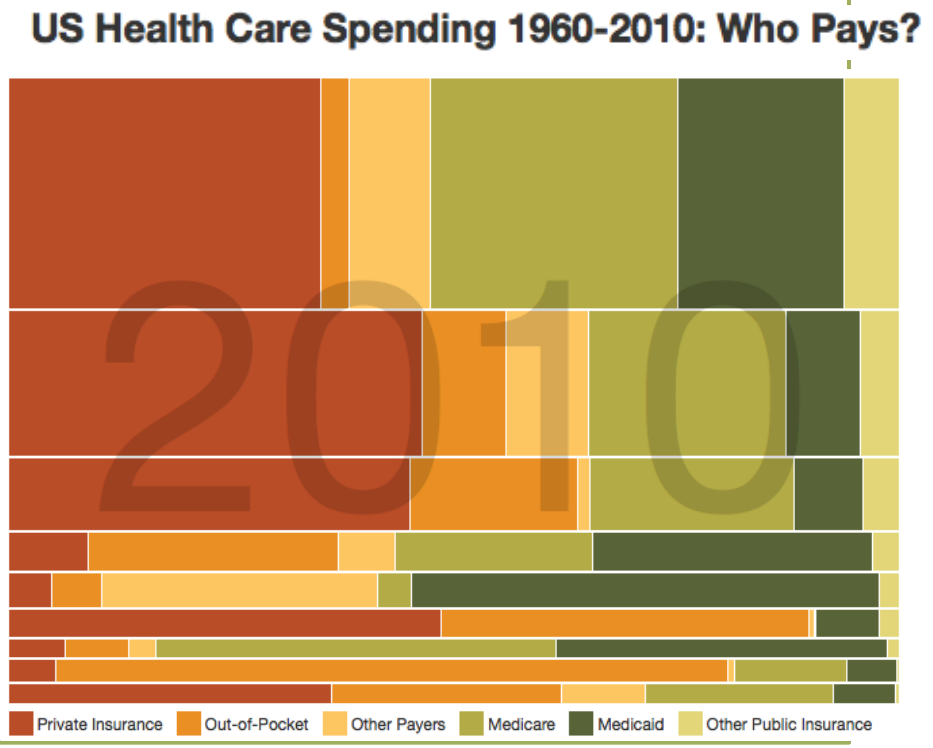
Graphical Elements in Clinical Laboratory Reports

- Graphical elements can rapidly convey large amounts of information



flowingdata.com

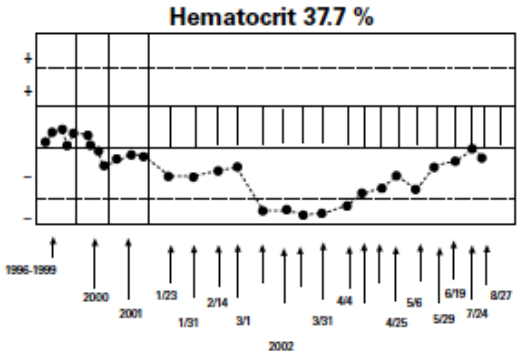


Graphical Elements in Pathology Reports

- Some graphical elements are standard

Comprehensive Graphic-Based Display of Clinical Pathology Laboratory Data

John Bernard Henry, MD, and Karen C. Kelly



- Format Matters
  - Synoptic reports

Formatting Pathology Reports

Applying Four Design Principles to Improve Communication and Patient Safety

Paul N. Valenstein, MD

Specialty labs are doing it

BONE MARROW: INCREASED IMMATURE MYELOMONOCYTIC CELLS INDICATIVE OF ACUTE MYELOID LEUKEMIA, M4 OR M5 SUBTYPE.

Comments:

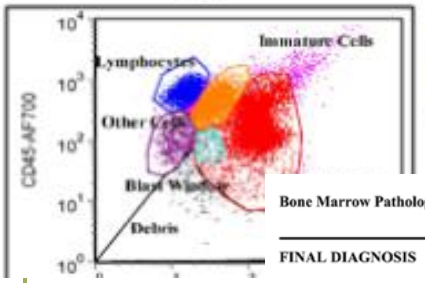
These findings are indicative of either an Acute Myelomonocytic Leukemia or an Acute Monoblastic Leukemia. If clinically indicated, evaluation of a sample by FISH or cytogenetics would further support this diagnosis. Clinical, morphologic and cytogenetic correlation is recommended for full interpretation.

Clinical History:

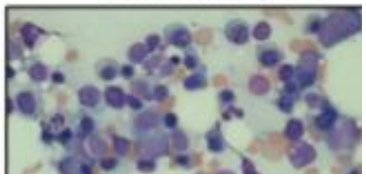
80-year old female.

Submitted Dx: PANCYTOPENIA **Cell Yield:** 11,600 cells/mm³ **Viability:** 96%

flow



bone marrow aspirate



Recurrence Score = 5

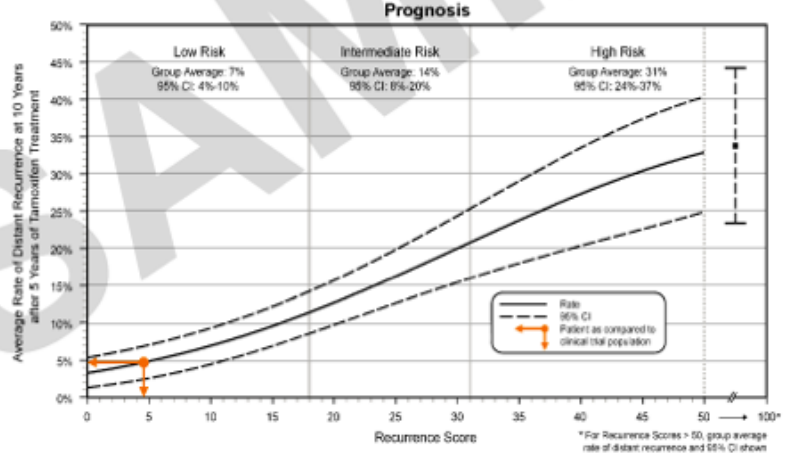
Test Results should be interpreted using the Clinical Experience information contained in this report which is derived from clinical studies involving patient populations with specific clinical features as noted in each section of the Clinical Experience. It is unknown whether the findings summarized in the Clinical Experience are applicable to patients with features different from those described.

CLINICAL EXPERIENCE: PROGNOSIS FOR NODE NEGATIVE, ER-POSITIVE PATIENTS

The Clinical Validation study included female patients with Stage I or II, Node Negative, ER-Positive breast cancer treated with 5 years of tamoxifen. Those patients who had a Recurrence Score of 5 had an Average Rate of Distant Recurrence of 5% (95% CI: 2%-7%)

The following results are from a clinical validation study of 668 patients from the NSABP B-14 study. *N Engl J Med* 2004; 351: 2817-26.

Recurrence Score vs Distant Recurrence in NODE NEGATIVE, ER-Positive Breast Cancer Prognosis



Node Negative

Bone Marrow Pathology Report

FINAL DIAGNOSIS

WHO Acute Myeloid Leukemia Not Otherwise Specified: FAB Acute Myelomonocytic Leukemia (M4)

Bone Marrow Biopsy, Aspirate and Particle Preparation:
1. Acute Myeloid Leukemia with marked hypercellularity, numerous blasts (67%) and eosinophilia (21%).
2. Reduced Trilineage Hematopoesis.

Peripheral Blood:
1. Acute Myeloid Leukemia with leukocytosis including numerous blasts (40%), monocytosis (25%), and eosinophilia (16%).
2. Anemia and thrombocytopenia.

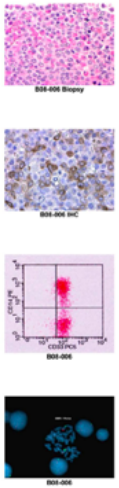
Flow Cytometry Interpretation

Flow cytometric immunophenotyping studies performed on bone marrow demonstrated numerous CD34 positive/CD117 positive myeloid blasts (14/22% positive); these cells coexpressed the myeloid markers CD13/33. Many expressed HLA-DR and TdT, also markers of myeloid immaturity. Also, there was a distinct population of cells that expressed the monocytoid marker, CD14.

Clinical History: A 30-year-old female without any significant past medical history, developed symptoms of sinus pressure and headache for approximately three weeks. These were thought to be sinusitis and treated with oral antibiotics (Bactrim) and antihistamines. Subsequently she developed gingival hyperplasia and was found to have a white blood cell count of over 70x10^9/L.

Microscopic Examination

Bone Marrow biopsy and aspirate were performed with the following remarkable and abnormal differential counts:



Technology

- Pilot projects to test an online enhanced electronic laboratory reporting system.
- Footnote to the LIS-version test result containing
  - URL
  - chart id number
  - Password
- PDF-format chart is generated and stored on a server
- Login information allowed tracking access

Study Design

- Evaluation of utilization patterns (number of views)
  - 48 different reportable tests
  - 22 months starting Nov 2009
  - 74,170 reports with graphical elements
- Analysis: Comparing groups of tests by attribute
  - Nature of graphical report (photograph, table, chart, etc.)
  - Total test volume
  - Time since implementation of enhanced report
  - Results (abnormal vs. normal)

ARUP LABORATORIES

Maternal Serum Screening, Integrated, Specimen #2

ARUP is an enterprise of the University of Utah and its Department of Pathology.

Patient Name: Spgen, 6
Date of Birth: December 13, 1973
Accession #: 10-014-100007
Date of Draw: January 14, 2010
Date Reported: January 15, 2010
Client Order ID:

ARUP Physician Services Client ID: 4070
321 TESTING ANSR EXTRACT
Salt Lake City, NY 84108
Referring Physician: Dr. Arup Arup

Patient Information Used In Risk Calculations:	
Maternal Age at Delivery:	36.5 yrs
Estimated Due Date	June 30, 2010
Gestational Age at Draw:	16 Weeks 1 Day(s)
Maternal Weight:	145 lbs
Maternal Race:	White
Number of Fetuses:	Singleton
Family History of neural tube defects:	No
Patient is medication-dependent diabetic:	No
Crown Rump Length:	5.00 cm

Marker	Measurement	MoM
AFP	20 ng/mL	0.59
hCG	30000 IU/L	1.13
uE3	0.50 ng/mL	0.53
Inhibin A	300 pg/mL	1.69
PAPP-A	800 mIU/L	0.54
NT	4.00 mm	3.51

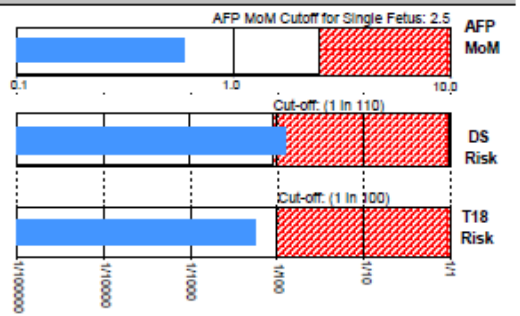
Sonographer Name: Amie Healy
Sonographer Cert #: P00943
Ultrasound Date: December 14, 2009

Interpretation:

Open Neural Tube Defects
Normal
Risk Before Test: 1 in 900
Risk After Test: <1 in 10000

Down Syndrome
Abnormal
Risk Before Test: 1 in 210
Risk After Test: 1 in 80 *

Trisomy 18
Normal
Risk Before Test: 1 in 2100
Risk After Test: 1 in 180



Comments:

Assuming the patient information listed is correct, this maternal screen is ABNORMAL. Other possible outcomes of abnormal screens include: normal pregnancy, intrauterine fetal demise or missed abortion. If you have questions regarding this screen, please call Genetics at 800-242-2787 ext. 2020.

This is a screening test for Down syndrome, trisomy 18 and open neural tube defects. It will not detect all cases of these disorders, and its ability to identify other chromosome disorders has not been established.

The PAPP-A 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 ARUP Laboratories. The U.S. Food and Drug Administration (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. ARUP is authorized under Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing.

Risk estimates determined using Integrated Test Technology under license from Intema Ltd, UK.

ARUP LABORATORIES

500 Chipeta Way, Salt Lake City, Utah 84108-1221
phone: (801) 583-2787 toll free: (800) 242-2787
fax: (801) 583-2712 web: www.aruplab.com

ARUP is an enterprise of the University of Utah and its Department of Pathology.

Enhanced Report for Chromosome Analysis

Accession #:	**123-456-78899**	**ARUP Test Client**	
Patient:	**Jane Doe**	**123 Anywhere Street**	
DOB:	**01/01/1900**	**Smalltown, UT 01234**	
Sex:	**Female**		
Ordering Provider:	**ARUP Test Physician**		
Completion Date:	**09/10/2009 14:19:23**		

Specimen Received:

Specimen type: Placental Tissue (Villi)
Reason for referral: R/O Abnormal Pregnancy
Test performed: Chromosome Analysis

Chromosome Results:

92,XXXX

Diagnostic Impression:

Metaphase cells analyzed from cultures of tissue revealed a female chromosome complement with 92 chromosomes due to an entire extra diploid (46) set of chromosomes resulting in tetraploidy. Tetraploidy is not an uncommon finding in first trimester pregnancy loss.

Recommendation:

Genetic counseling

This study was performed by the University of Utah Cytogenetics Program at ARUP Laboratories.

This result has been reviewed and approved by
Jia Xu, M.D., FACMG
Electronic Signature

Laboratory Analysis

Number of cells counted: 20
Number of colonies counted: N/A
Number of cells analyzed: 5
Number of cells karyotyped: 5
ISCN Band level: 425
Banding Method: G-Banding

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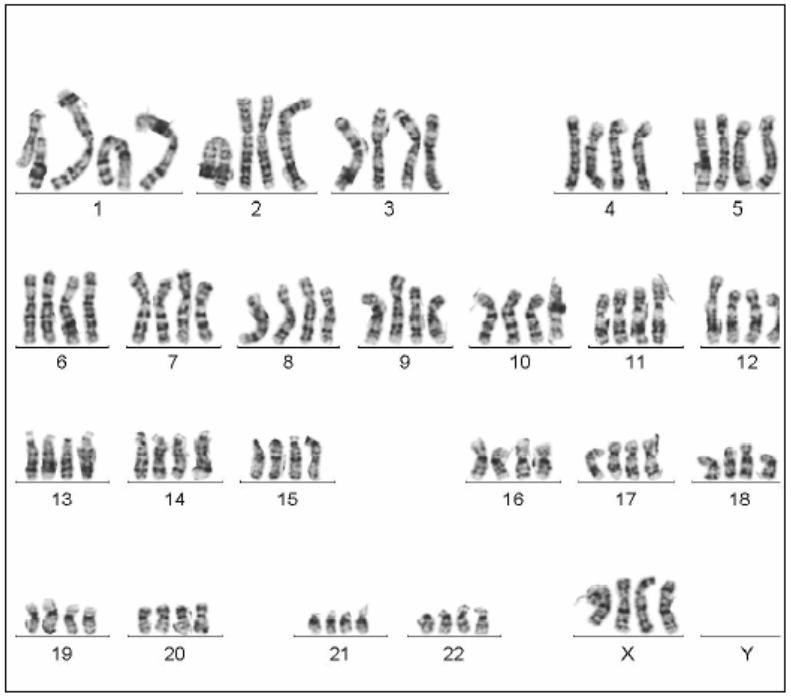
ARUP is an enterprise of the University of Utah and its Department of Pathology.

Patient: Jane Doe
DOB: 01/01/1900
Accession #: 123-456-78899
Sample Type: Placental Tissue (VIII)
Slide #: 0001



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fax: (801) 583-2712 web: www.aruplab.com
Sherrie L. Perkins, MD, Laboratory Director

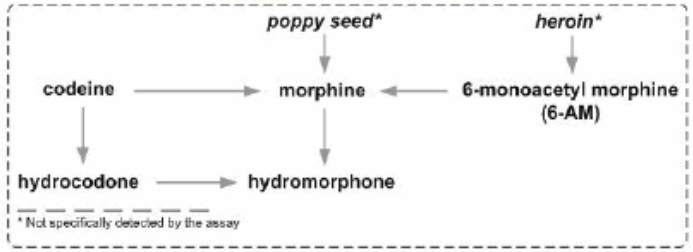
Accession:	11-136-100864	**Collection Date:**	5/16/2011 7:09:00AM	**ARUP Physician Services**	
Patient:	ARUPTEST, 17594 20YF	**Received In Lab:**	5/16/2011 7:10:00AM	**321 TESTING ANSR EXTRACT**	
DOB:	2/28/1990 12:00:00AM	**Completion Date:**	5/16/2011 7:11:54AM	**Salt Lake City, NY 84108**	
Age:	21			**Physician:**	TEST, DR
Gender:	F				

Opiates Screen in Urine by LC-MS/MS

Analyte	Cutoff	Result	Units	Notes
Opiates, Screen Urine	300	Positive	ng/mL	This result was obtained with an immunoassay. The actual concentration at which the screening test is "POSITIVE" reflects the sum of the cross-reacting parent drug(s), and drug metabolite(s) detected by the immunoassay. This sum must exceed the cutoff concentration to be reported as "POSITIVE." Confirmation testing by LC-MS/MS may be indicated if the result is inconsistent with clinical expectations.

Simplified Opioid Metabolic Pathway

Drug Analytes Half-Lives (Urine and Plasma)



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Age:	21			**Physician:**	TEST, DR
Gender:	F				

EVALUATION OF ADHERENCE TO PRESCRIPTION OPIOIDS

Results	Possible Interpretations	Considerations
Expected Drug(s) Identified	The patient adhered to the prescribed medication plan.	Dose compliance cannot be determined reliably with urine.
	The patient has adulterated his or her urine (eg, added drug directly to the urine).	A high concentration of parent drug coupled with the absence of common metabolite(s) may suggest adulteration of the urine specimen. Retest with a new specimen.
	The unexpected drug is a metabolite of an expected drug.	Consult metabolic pathway diagram; ratios of parent opioids and possible metabolite(s) may suggest whether the patient used one drug or more than one drug.
Unexpected Drug(s) Identified	The unexpected drug is an impurity of an expected drug product.	Pharmaceutical impurities are usually observed at concentrations < 5% of the primary drug concentration. If concentration is > 5%, retest with a new specimen.
	An unexpected drug was dispensed to the patient.	Verify prescription records.
	The patient used non-prescribed or otherwise undisclosed drug(s).	Discuss with patient to verify.
Expected Drug(s) NOT Identified	The patient did NOT adhere to the prescribed medication plan.	Discuss with patient to verify.
	The patient adhered to the medication plan but has unusual pharmacokinetics or a clinical condition that compromises drug absorption.	Test with timed blood specimens to evaluate individual patient absorption/clearance factors (eg, metabolic conditions or drug interactions).
	The patient eliminated the drug prior to specimen collection.	Consult drug pharmacokinetics and discuss with patient to verify time of last dose relative to specimen collection.
	The patient's urine was dilute, such that the concentration of expected drug analytes fell below assay detection limits.	Consider repeat testing with a new specimen and/or verify urine dilution with creatinine or specific gravity testing.
	The test performed does not detect the drug(s) of interest.	Compare the list of drugs detected by the assay with the list of drugs expected.

For more information about:

Opioids and related testing, refer to Opioids topic in ARUP Consult. *(arupconsult.com/Topics/Opioids)*

Drug testing and monitoring, refer to Drug Testing topic in ARUP Consult. *(aruplab.com/DrugTesting)*

Available testing for pain management and drug monitoring, refer to the ARUP Laboratory Test Directory.

(aruplab.com/Testing-Information/lab-test-directory.jsp)

Drug half-lives in urine and blood specimens, refer to the Drug Analytes Detected in Plasma and Urine table.

(aruplab.com/Lab-Tests/resources/da-plasma-urine.pdf)

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ARUP is an enterprise of the University of Utah and its Department of Pathology.

Enhanced Report for FISH Testing

Accession #:	**123-456-78899**	**ARUP Test Client**
Patient:	**Jane Doe**	**123 Anywhere Street**
DOB:	**01/01/1900**	**Smalltown, UT 01234**
Sex:	**Female**	
Ordering Provider:	**ARUP Test Physician**	
Completion Date:	**09/10/2009 14:19:23**	

Specimen Received:

```
Specimen Type:        Bone marrow
Reason for Referral:  COG AML Panel
Test Performed:       FISH, Interphase
```

FISH Results:

```
ABNORMAL FISH RESULT
nuc ish 8q22(RUNX1T1x3),21q22(RUNX1x3)(RUNX1T1 con
RUNX1x1)[182/200]

NORMAL FISH RESULT
nuc ish 5q31(EGR1x2)
        7cen(D7Z1x2),7q31(D7S486x2)
        11q23(MLLx2)
        16q22(CBFBx2)
```

Diagnostic Impression:

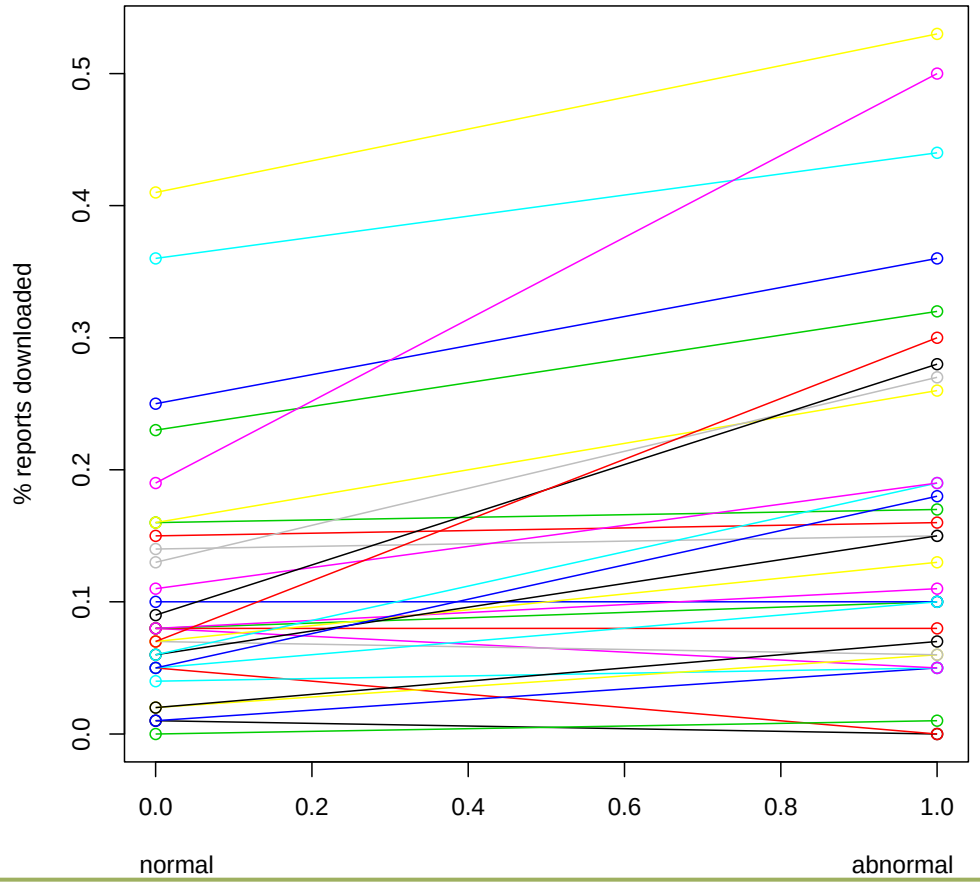
```
Fluorescence in situ hybridization (FISH) analysis with the
EGR1, D7S486, RUNX1/RUNX1T1 (also known as AML1/ETO), MLL,
and CBFB probes (Abbott Molecular) showed evidence of a fusion
of RUNX1 and RUNX1T1 in 182/200 cells scored (91%).  The signal
pattern
was suggestive of a 3-way translocation such as t(8;21;var).  The
pending chromosome study will likely identify the additional
chromosome involved in this translocation.  A t(8;21;var) is
observed in approximately 3% of cases with a RUNX1/RUNX1T1
fusion.

FISH analysis with the remaining probes (EGR1, D7S486, MLL and
CBFB) showed no evidence of abnormalities involving these
loci in 200 cells scored for each probe.
```

Results

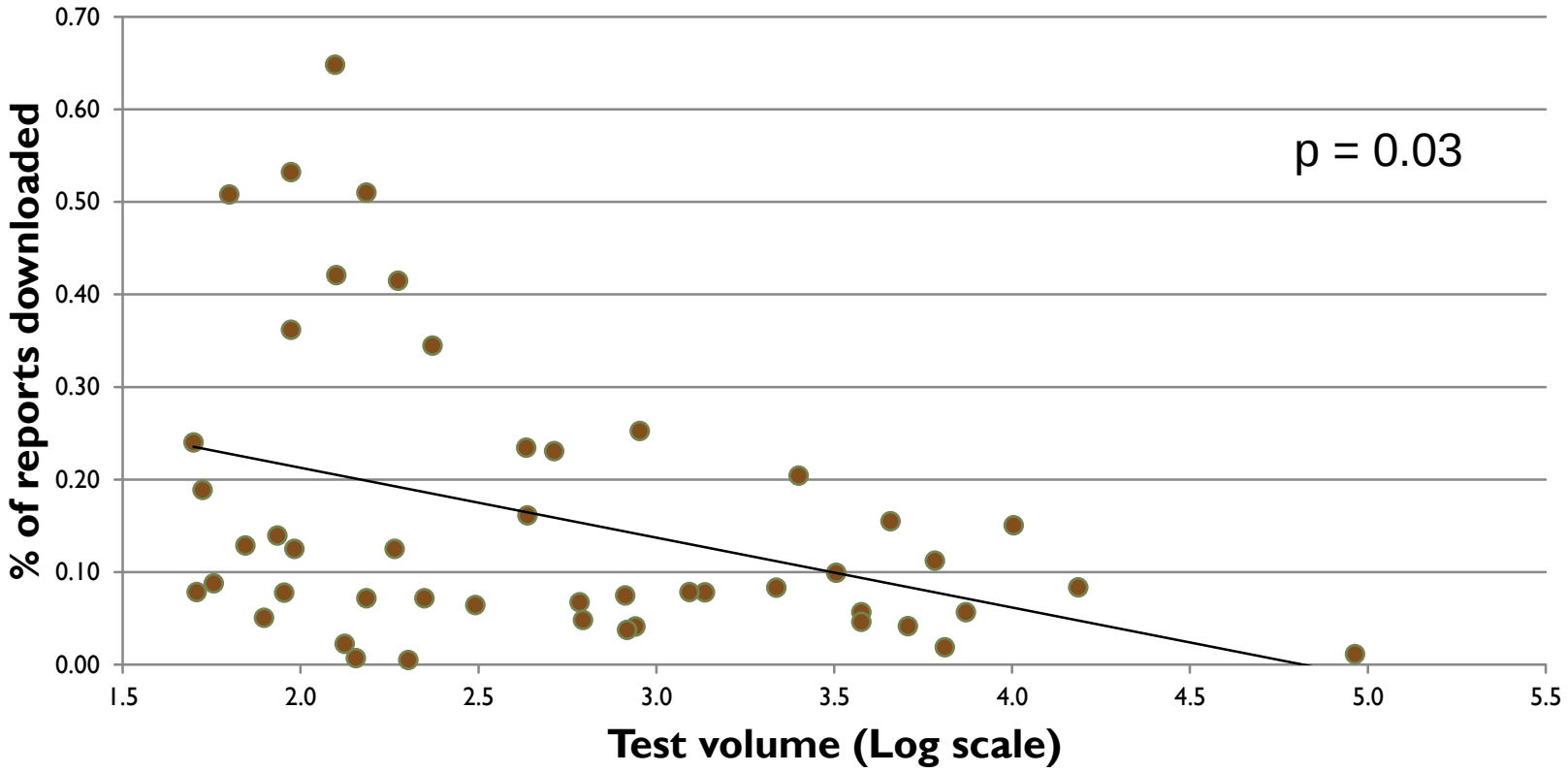
Group	N	Overall %	Median	High	Low	Average (meta- analysis)	95% CI	p-value for within group heterogeneity
All Tests	**48**	**5.1%**	**8.6%**	**64.8%**	**0.5%**	**13.3%**	**[10.6%; 16.3%]**	**< 0.0001**
Other	13	10.2%	34.5%	64.8%	5.1%	27.9%	[21.4%; 34.9%]	< 0.0001
Onc Cytogenetics	4	15.0%	14.5%	16.1%	7.8%	14.7%	[12.7%;16.9%]	0.198
Const Cytogenetics	7	12.3%	8.8%	41.5%	7.2%	14.5%	[9.3%; 20.7%]	< 0.0001
Const FISH	4	10.9%	14.4%	23.4%	6.7%	13.8%	[7.7%; 21.3%]	< 0.0001
Genomic Microarray	5	7.4%	12.5%	24.0%	4.1%	10.4%	[6.3%; 15.3%]	< 0.0001
Maternal Screen	6	2.1%	4.4%	15.5%	1.1%	4.7%	[1.7%; 9.1%]	< 0.0001
Onc Fish	9	5.5%	4.8%	12.9%	0.5%	4.6%	[2.8%;6.8%]	< 0.0001

Normal / Abnormal Results

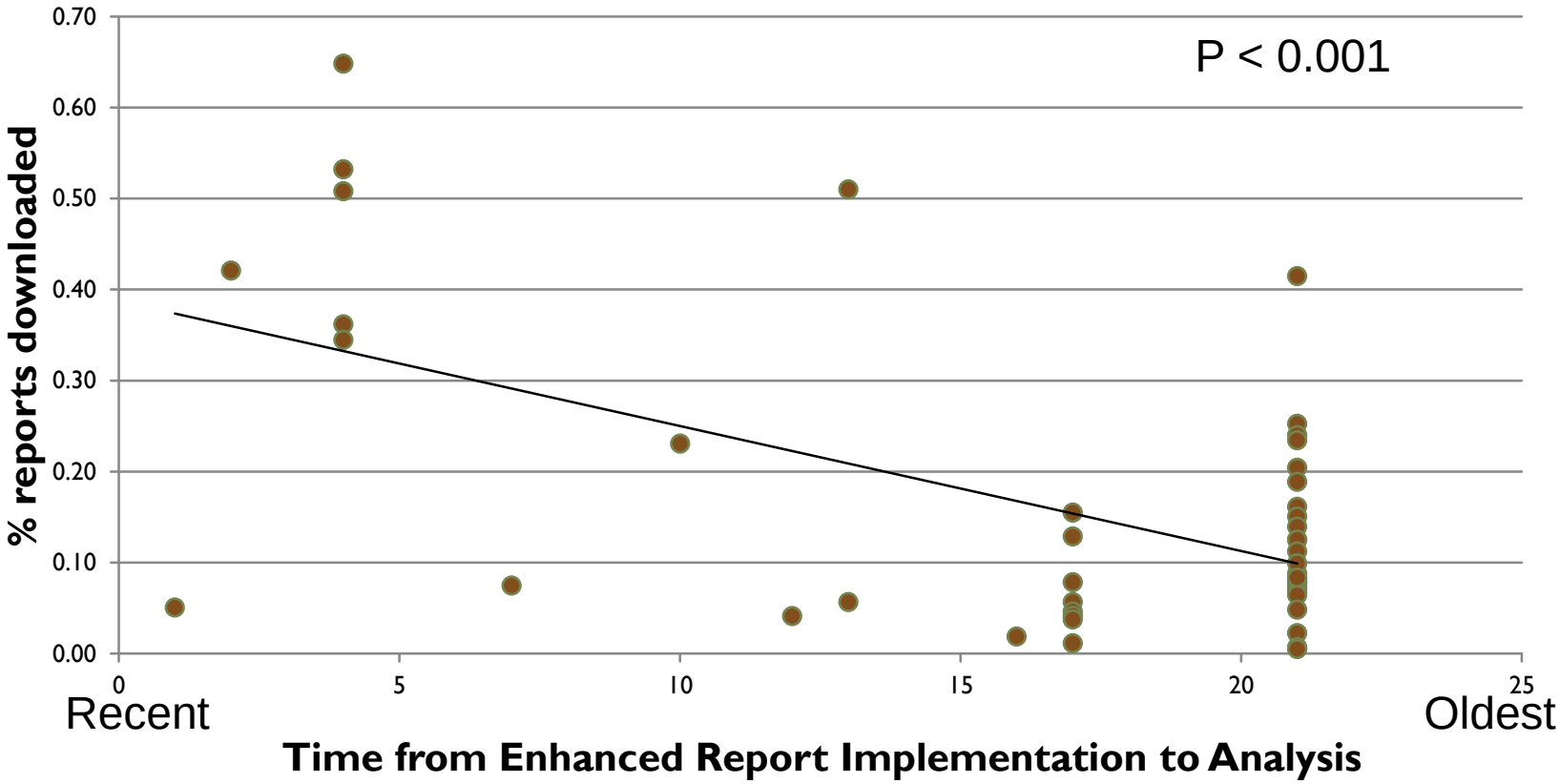


$p < 0.01$

Test volume
Common vs. Esoteric



Recent Implementation of Enhanced Report



Conclusions

- Graphical information may be clinically utilized/useful in certain situations
  - Less frequently ordered tests
  - Abnormal results
- Novelty factor
- Between-test heterogeneity was high even within groups of similar tests
- Graphical elements that reinforce information already contained in text based reports not used often

Acknowledgements

- ARUP Laboratories
- University of Washington, Department of Laboratory Medicine

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Onc Cytogenetics	4	15.0%	14.5%	16.1%	7.8%	14.7%	[12.7%;16.9%]	0.198
Const Cytogenetics	7	12.3%	8.8%	41.5%	7.2%	14.5%	[9.3%; 20.7%]	< 0.0001
Const FISH	4	10.9%	14.4%	23.4%	6.7%	13.8%	[7.7%; 21.3%]	< 0.0001
Genomic Microarray	5	7.4%	12.5%	24.0%	4.1%	10.4%	[6.3%; 15.3%]	< 0.0001
Maternal Screen	6	2.1%	4.4%	15.5%	1.1%	4.7%	[1.7%; 9.1%]	< 0.0001
Onc Fish	9	5.5%	4.8%	12.9%	0.5%	4.6%	[2.8%;6.8%]	< 0.0001