

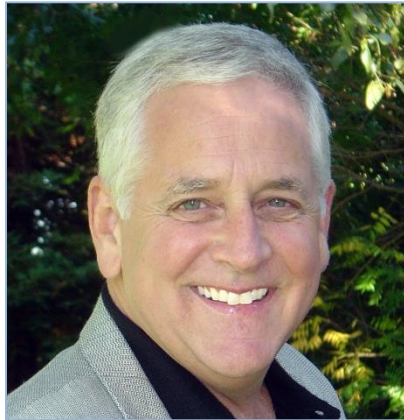


# MicroFISH<sup>®</sup> Assay System

## Making FISH Simple and Cost-effective



# Speakers



**Jim Stanchfield, Ph.D.**  
**Founder and CEO**  
SciGene, Sunnyvale, CA



**Eric Crawford, Ph.D., FACMG**  
**Senior Director**  
Genetics Associates, Nashville, TN

# Presentation Outline

Product Review

MicroFISH Assay System Video

20,000 Patient Study by Genetics Associates

Humidity Effects on Probe Hybridization

Clinical Validation of Scorpion for Automated MicroFISH Slide Prep

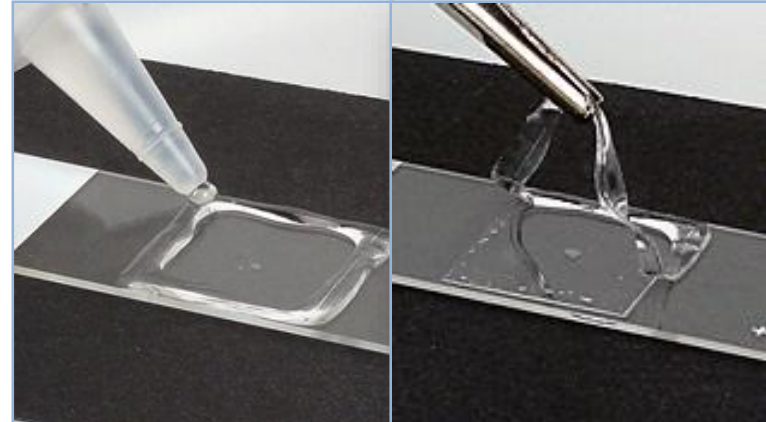
# Product Review

# SciGene Simplifies FISH

## Innovative Reagents



**CytoZyme™ Stabilized Pepsin**



**CytoBond® Coverslip Sealant**



**FISH Wash Buffers**

# SciGene Simplifies FISH Slide Processing Instruments



**CytoBrite® Slide  
Incubation System**

**Little Dipper® Processor**

**CytoBrite® Slide Oven**

# MicroFISH Video



<https://www.youtube.com/watch?v=oYNIIt2JACQ8>

# 20,000 Patient Study



# Over 20,000 Patient Samples Analyzed 2015 – Present

Panel	#
MDS	6300
MPN	5250
MM	2625
CLL	3150
AML	1575
Lymphoma	1575
<b>Total</b>	<b>20,475</b>

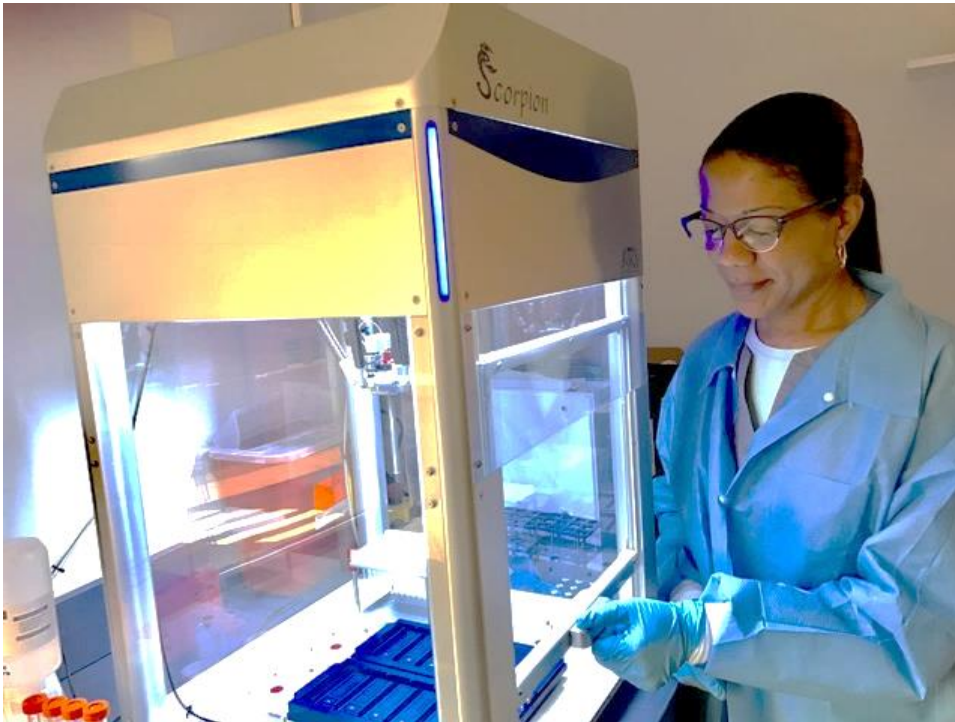


# Over 70,000 Test Performed (Avg. 1% Resets)

Probe	Tests
5q	10500
7q	9500
8	12000
20q	9500
BCR;ABL1/ASS1	5000
KMT2A	2500
IGH;MAF	1500

Probe	Tests
ATM	1400
12	1000
13q	5500
TP53	4500
IGH	1500
1p/1q	4000
FGFR3;IGH	1500

# Simple Workflow



- One Technician
- 200 Samples / Week

# MicroFISH Assay System

## Labor Economics

Cases	Step	Hands-on Time (min)		Time Savings	
		* Standard Method	MicroFISH	Minutes	Hours
10	Slides Processed	30	10		
	Probe Addition + Coverslip	12	4	8	
	Coverslip Removal and Wash	70	0	70	
	DAPI and Coverslip	5	1	4	
	<b>Total</b>	<b>87</b>	<b>5</b>	<b>82</b>	<b>1.4</b>

5000	Slides Processed	15000	5000		
	Probe Addition + Coverslip	6000	2000	4000	
	Coverslip Removal and Wash	35000	0	33000	
	DAPI and Coverslip	2500	500	2000	
	<b>Total</b>	<b>43500</b>	<b>2500</b>	<b>39000</b>	<b>650</b>

\* 6 probe panel/2 samples per slide

# Humidity Effects on Probe Hybridization

# *What Effect does Lower Humidity During Probe Hybridization have on Probe Signals ?*

**Probe Dilution Study** — compare signal intensities on slides using probes diluted to varying degrees and incubated at 95% and 50% RH.

## Method:

1. Dilute probe in hybridization buffer to the following final concentrations: 100%; 50%; 20% and 4%
2. Set up two sets of MicroFISH Slides for three probes:
  - CytoCell ATM;
  - CytoCell 4/14
  - Abbott 11/14
3. Use 4 wells per probe; 1 well for each dilution
4. Incubate one set overnight at 37<sup>0</sup> C /95% RH
5. Incubate second set at 37<sup>0</sup> C /50% RH in a prototype humidified oven
6. Examine cells and take pictures without adjusting settings

# Prototype Humidified Oven

Temperature Controller

Humidity Controller

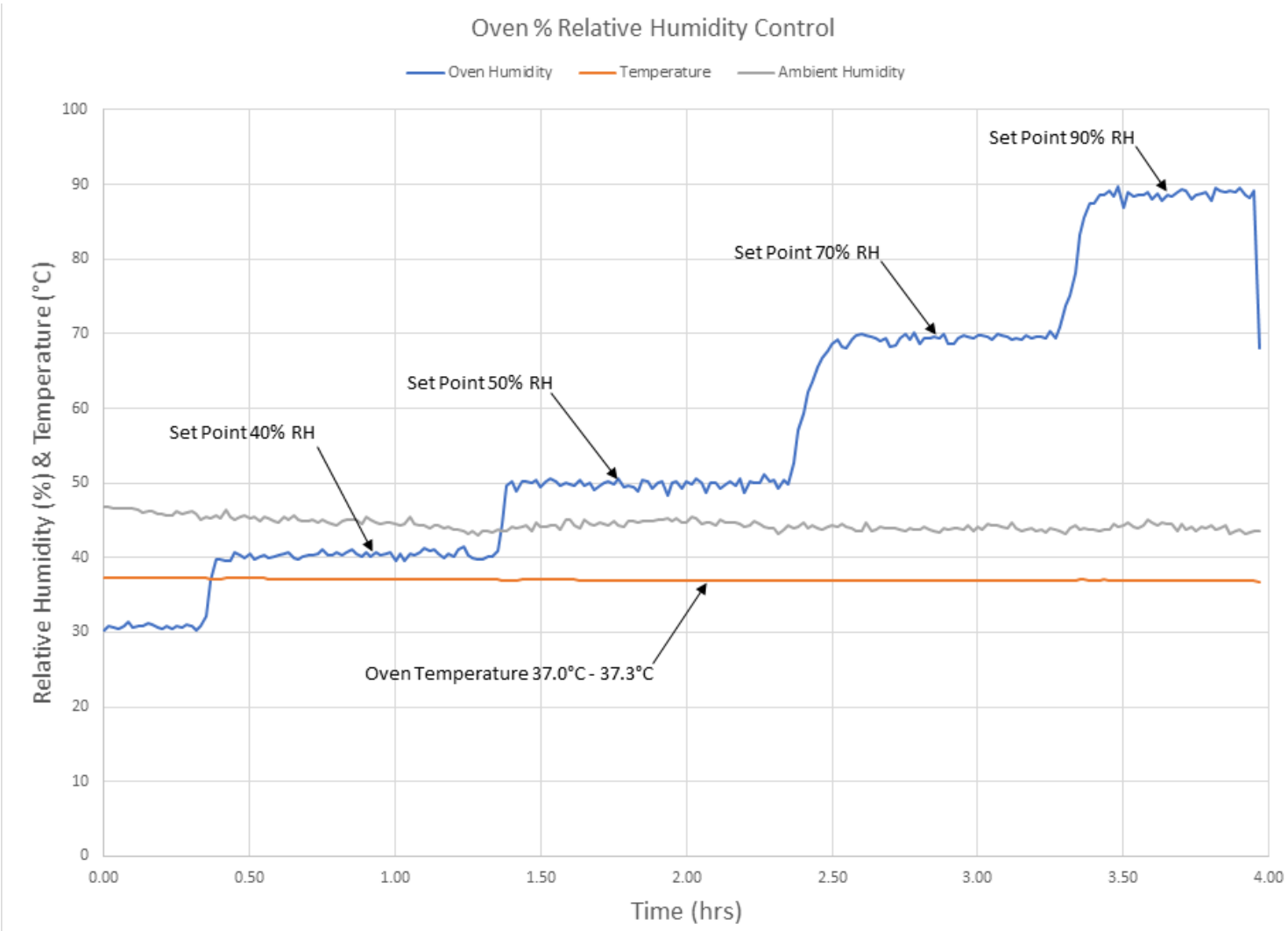
Nebulizer

Humidity Datalogger

Humidity Sensor



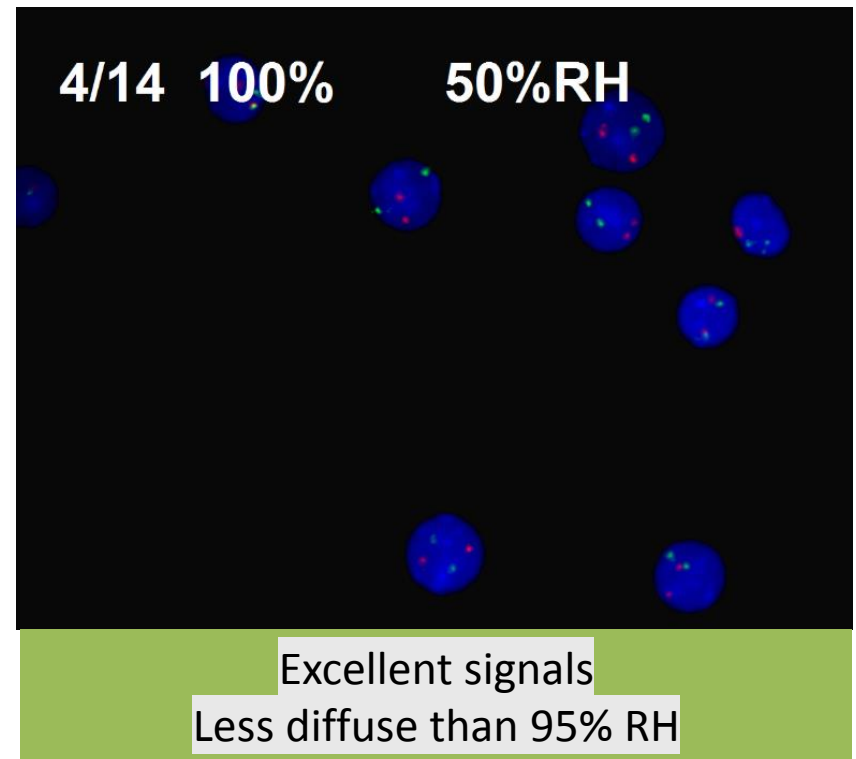
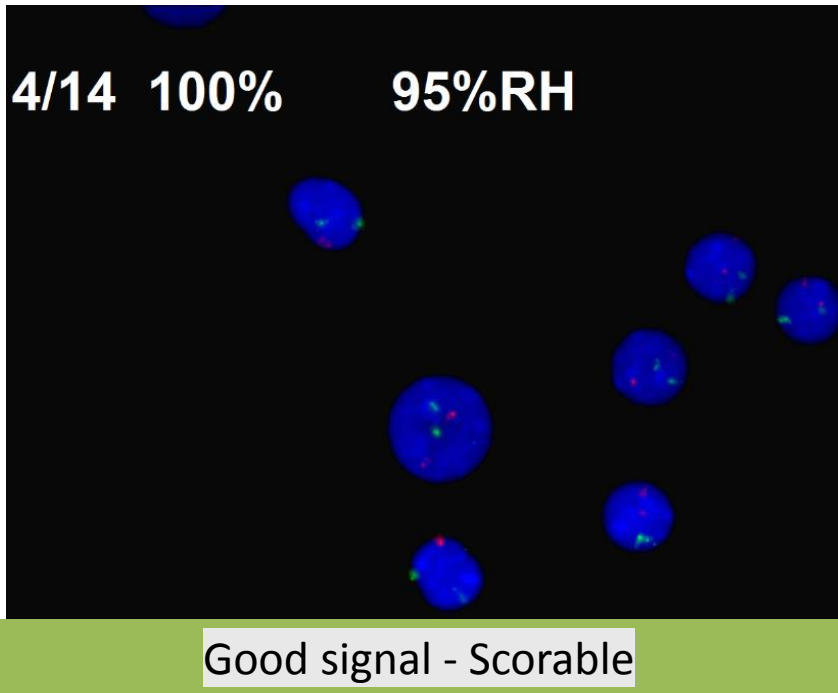
# Humidified Oven Precisely Controls Temperature and Humidity





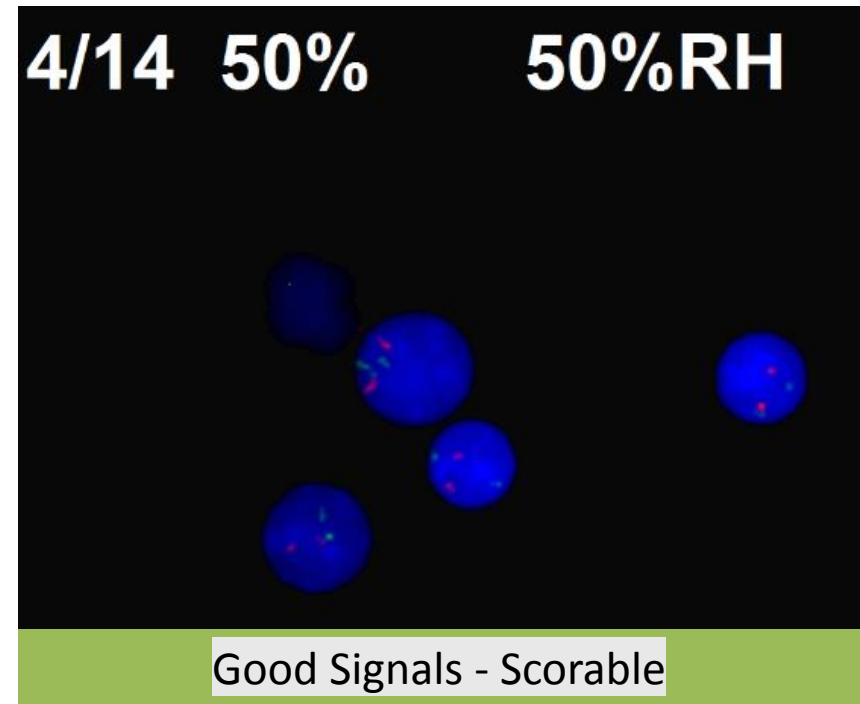
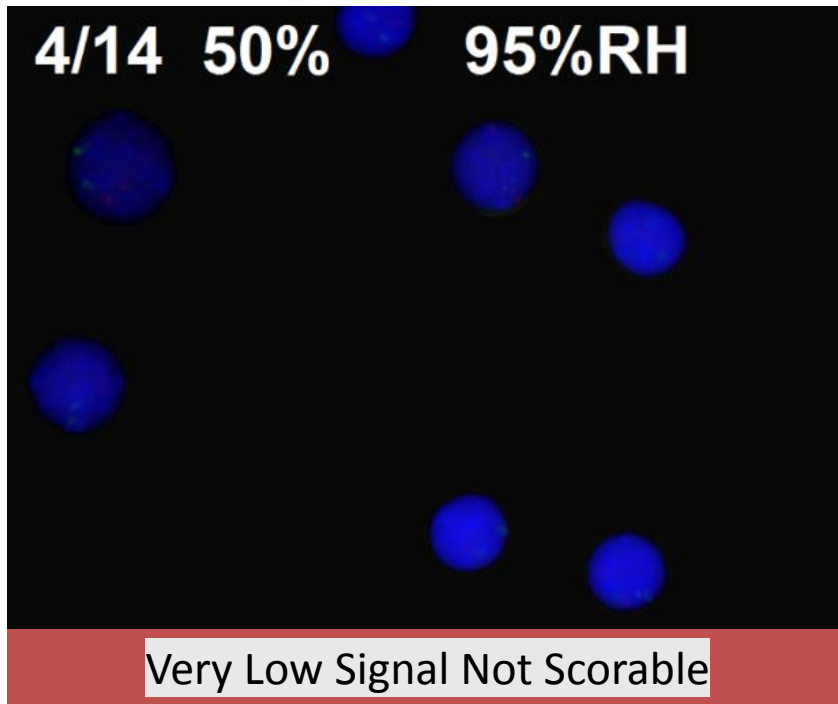
# Humidity Effects on Signal Intensities

## Probe 4/14 – No Dilution



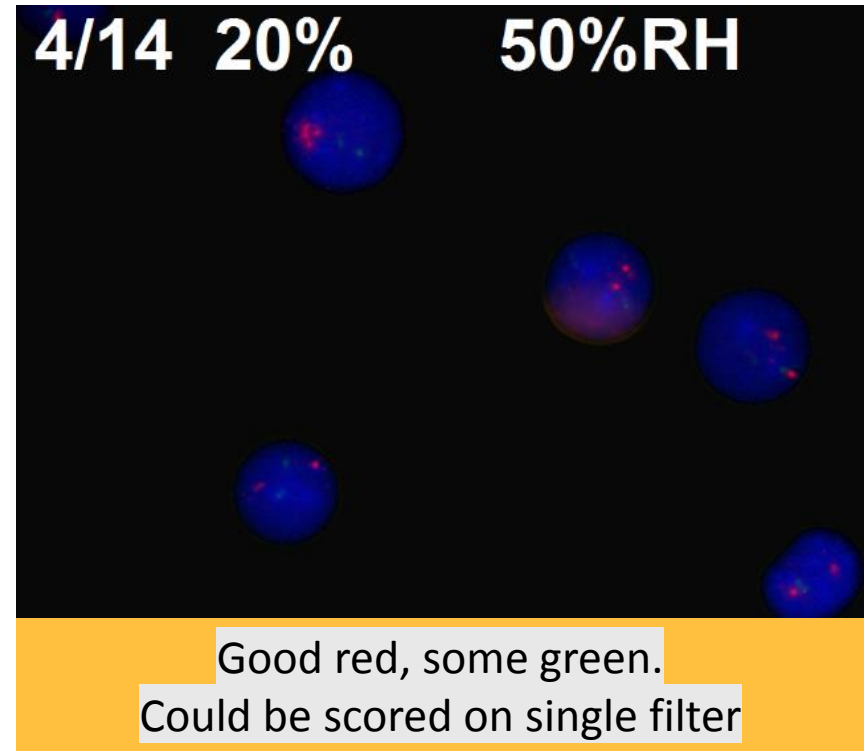
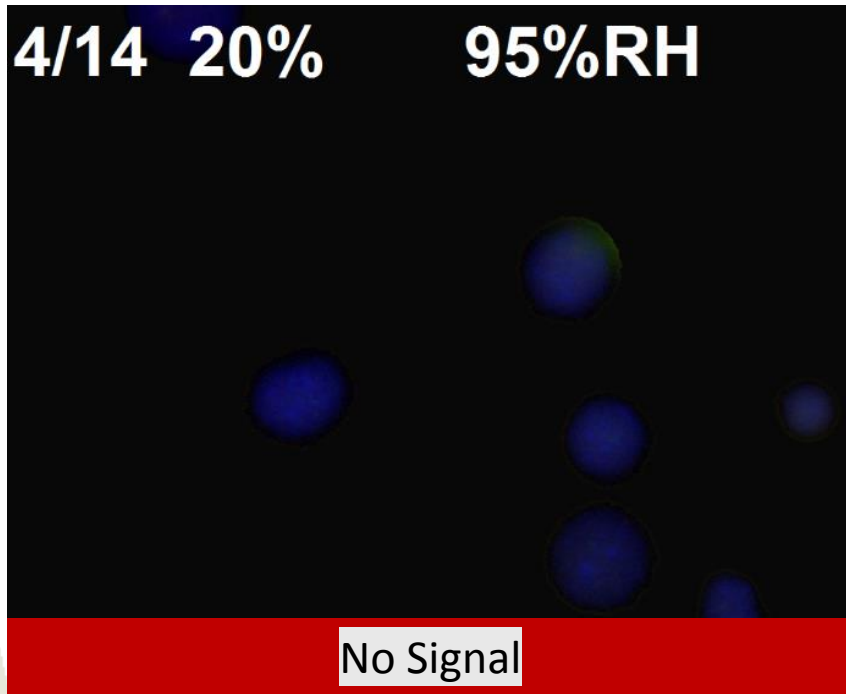
# Humidity Effects on Signal Intensities

## Probe 4/14 - 2X Dilution



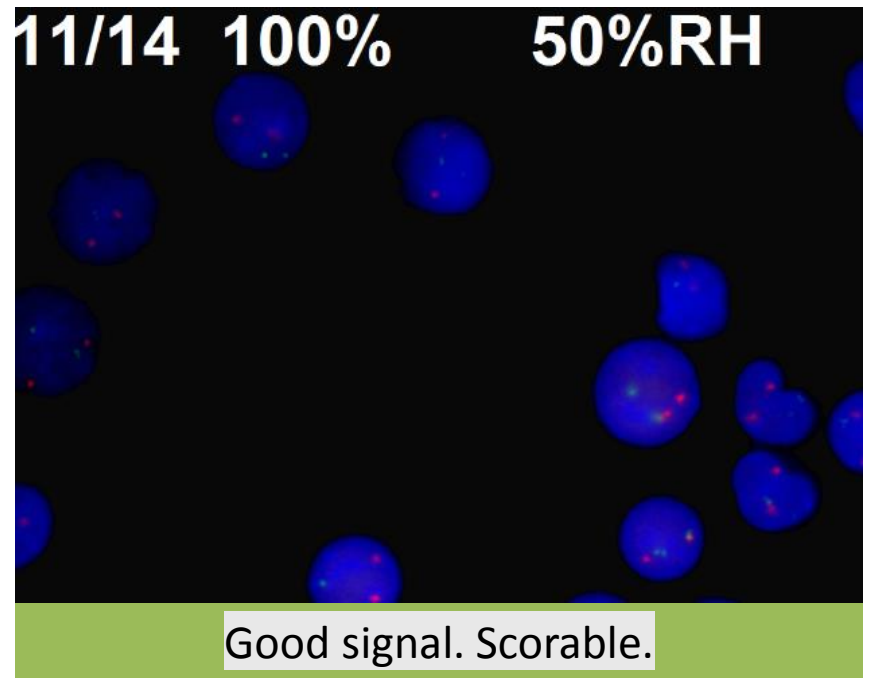
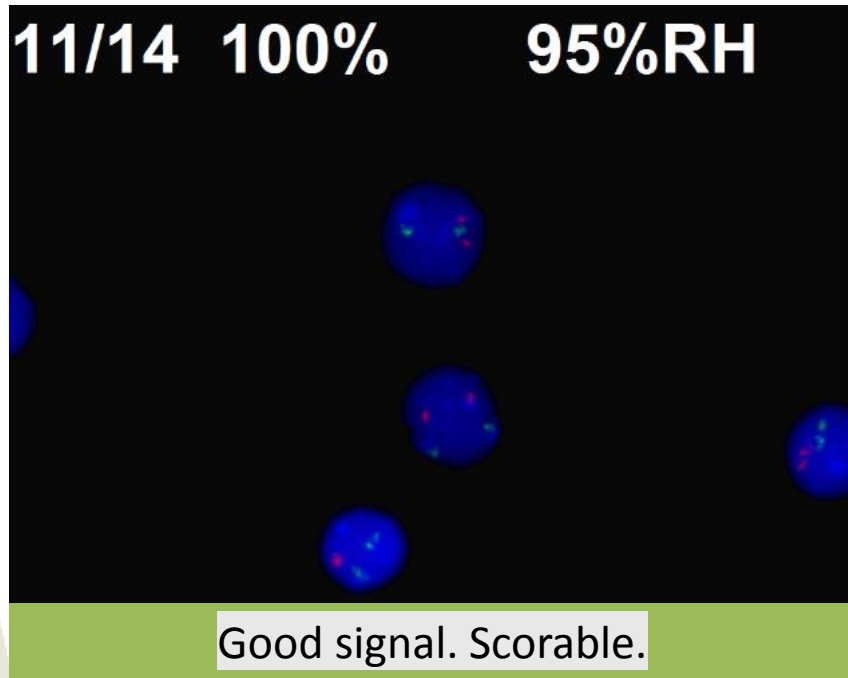
# Humidity Effects on Signal Intensities

## Probe 4/14 – 5X Dilution



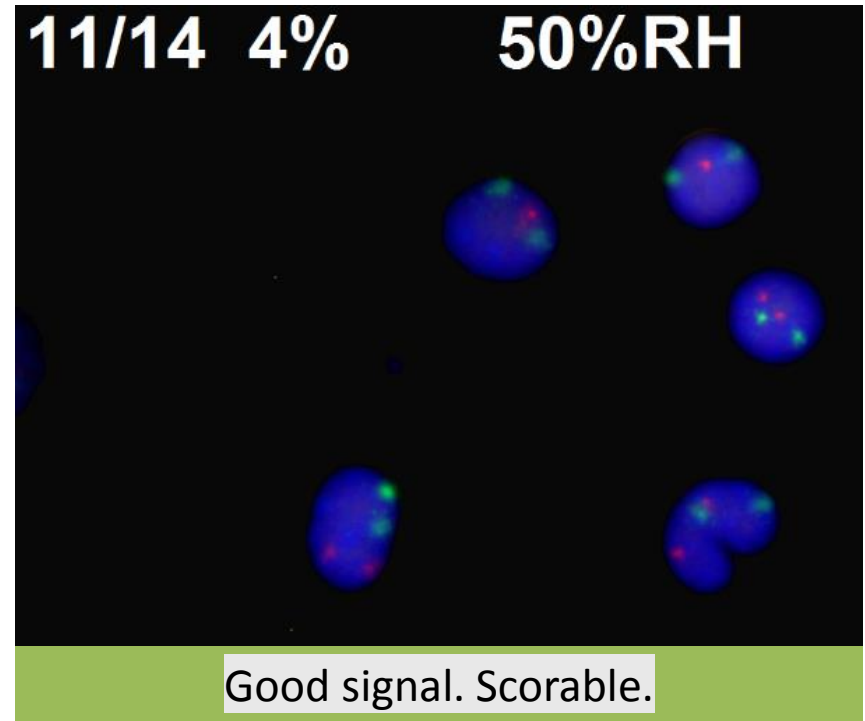
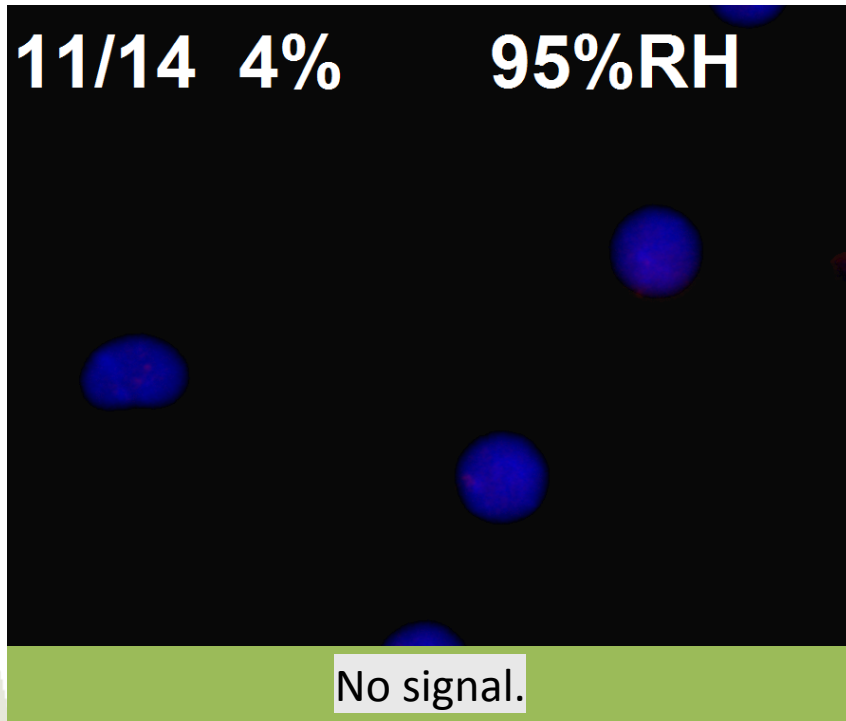
# Humidity Effects on Signal Intensities

## Probe 11/14 – No Dilution



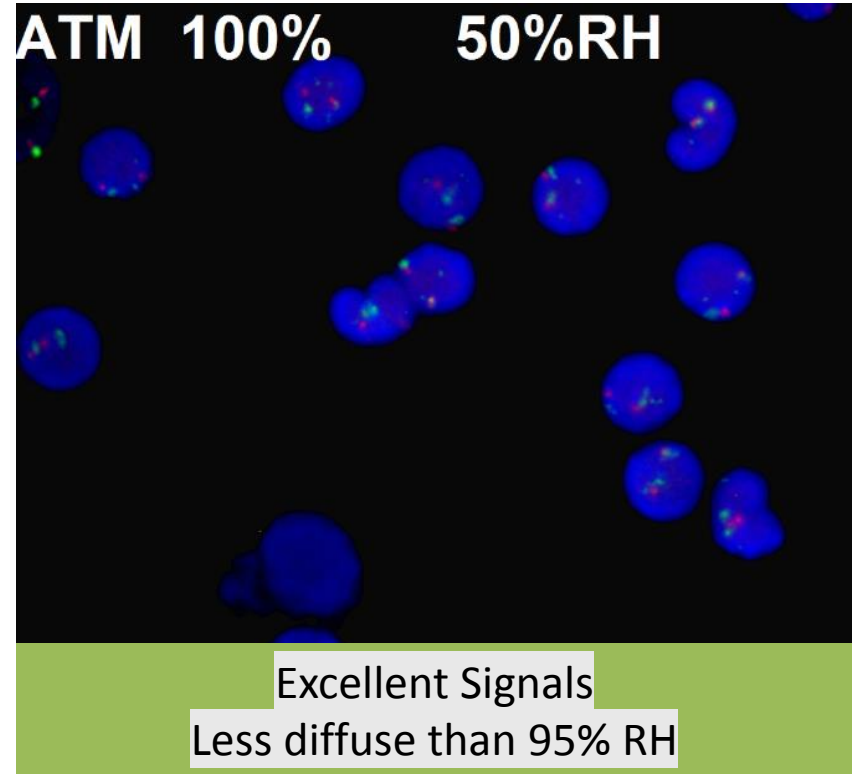
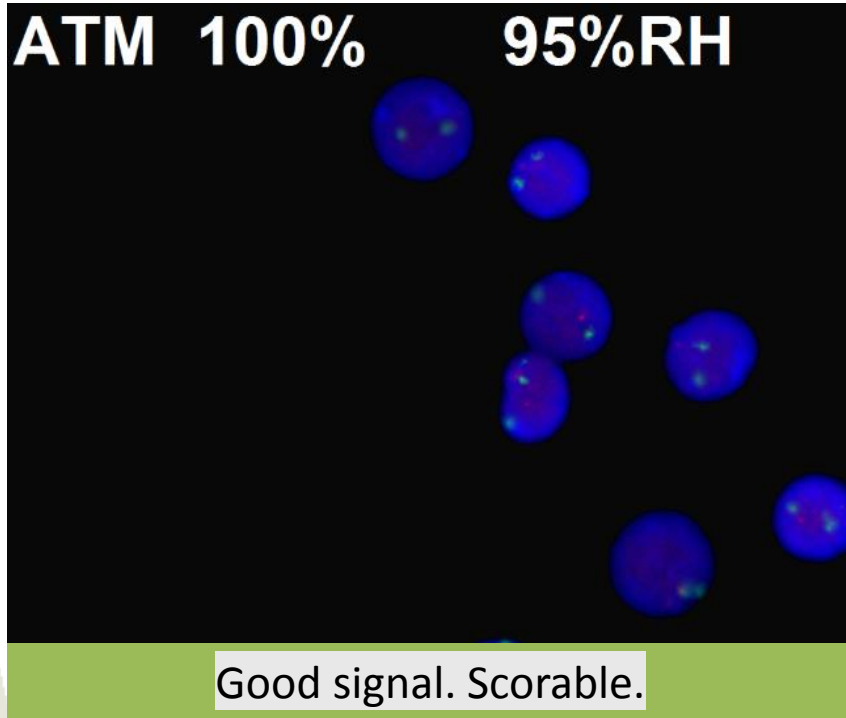
# Humidity Effects on Signal Intensities

## Probe 11/14 – 25X Dilution



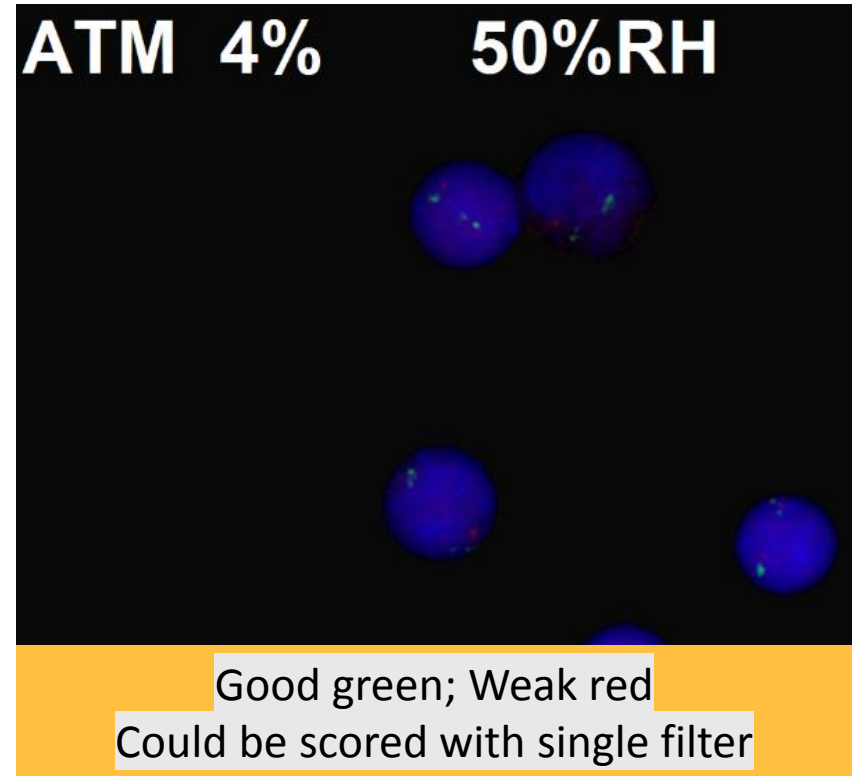
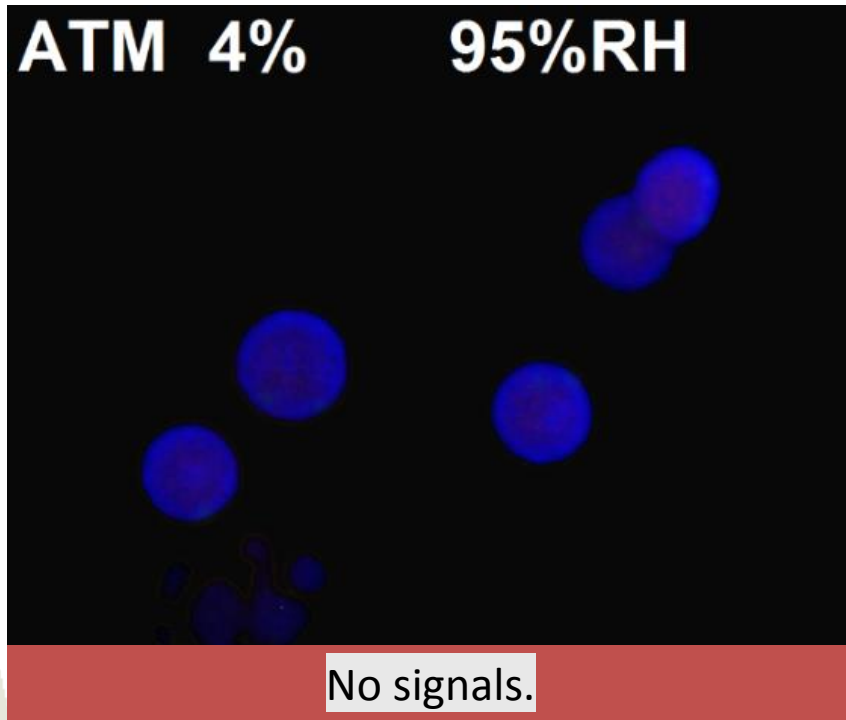
# Humidity Effects on Signal Intensities

## Probe ATM – No Dilution



# Humidity Effects on Signal Intensities

## Probe ATM - 25X Dilution

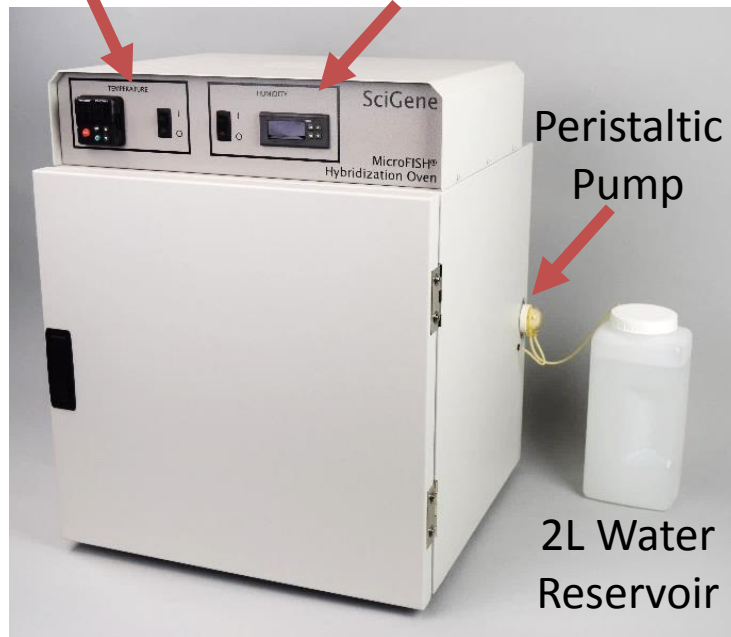


# MicroFISH Hybridization Oven

*Introduced @ ACMG 2017*

Temperature  
Controller

Humidity  
Controller



- Precisely controls humidity from 40-70% RH
- Controls incubation temperature from 32-45°C
- Supplies water to humidifier automatically
- Holds 162 MicroFISH Slides / 27 CytoBrite trays



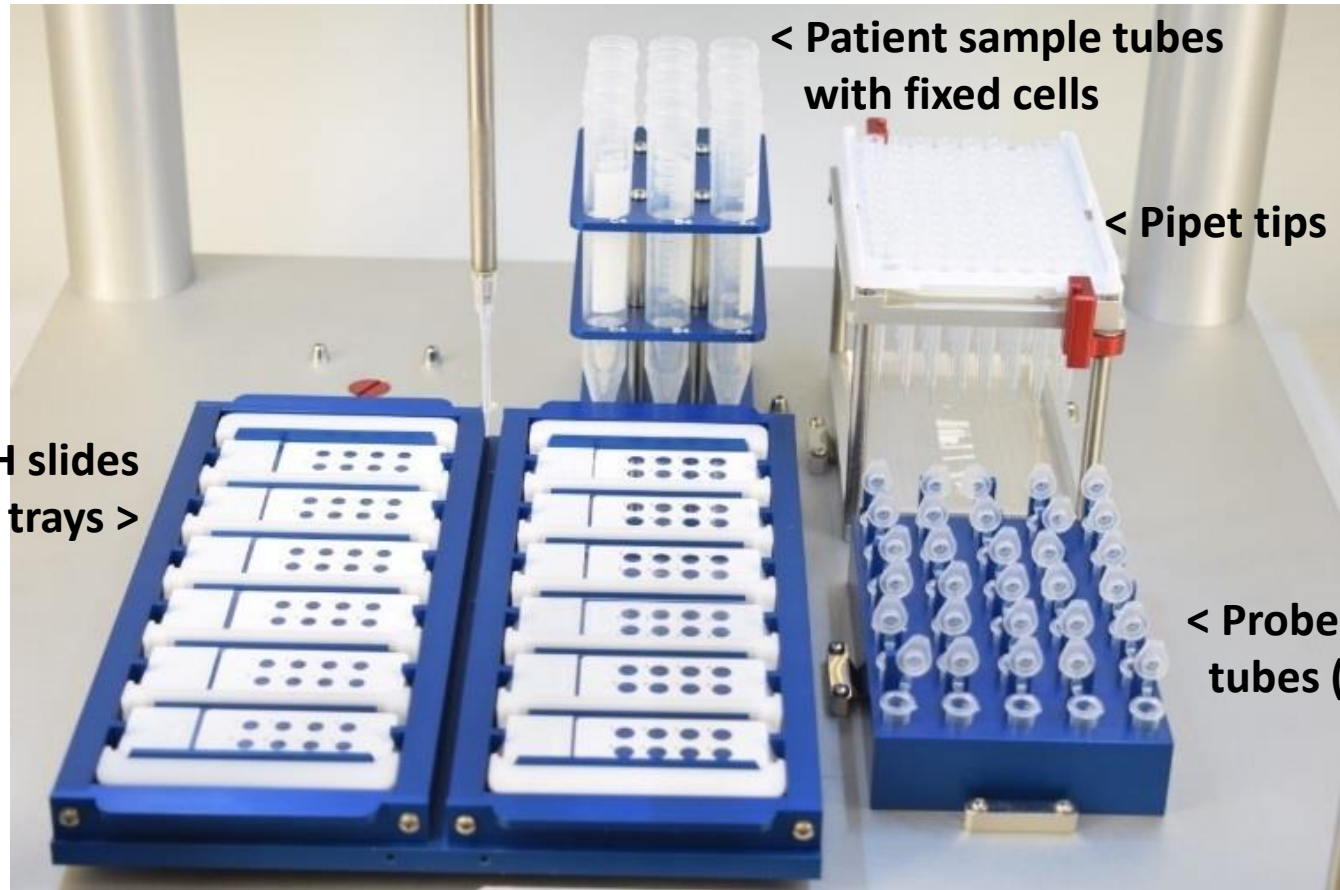
# Clinical Validation of Scorpion for Automated MicroFISH Slide Prep

# Scorpion Automates MicroFISH Slide Preparation



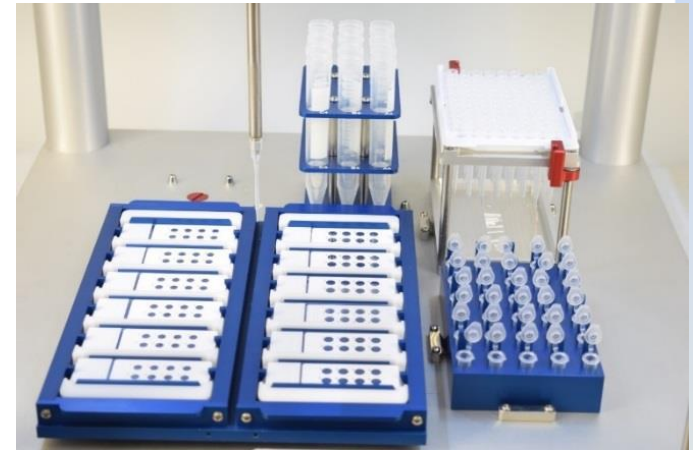
- Small footprint liquid handler
- Prepares 12 MicroFISH Slides ready for processing
- High throughput – 10 minutes per 12 slides
- Developed in partnership with Art Robbins Instruments

# Scorpion Preps 12 MicroFISH Slides



# Scorpion Preps 12 MicroFISH Slides

- Automates all pipetting steps
- Monitors probe inventory and volume
- Produces final score sheet for analysis
- Dispenses fixed cells from patient tubes
- Reliably pipets 1 $\mu$ l of probe to selected wells
- Accommodates up to 50 probe tubes



# Simple Scorpion for MicroFISH Automation

**Scorpion for  
MicroFISH**



**Automated**

Cell dropping  
10 min pause to dry  
Probe addition

**CytoBrite Slide  
Incubation  
System**



**Quick**

Heat @ 75°C

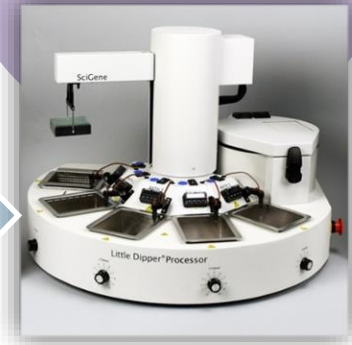
**MicroFISH  
Hybridization  
Oven**



**Overnight**

Hybridization @ 37°C  
in 50% RH

**Little Dipper  
Processor  
for FISH**



**Automated**

Coverslip removal  
Wash and Centrifuge dry

Apply DAPI  
& Coverslip



# MicroFISH Automated Workflow

## Patient Clinical Validation Study

### Clinical Cut-off Values

GAI Standard Method							
Probe	Normal	1r2g	1r1g	2r1g	3r3g	1r1g12f	1r1g1f
5q	95%	2%	1%				
7q	96%	1%	2%	1%			
8	96%				1%		
20q	95%	2%	2%	1%			
BCR;ABL1	93%					1%	1%
Automated MicroFISH Method							
Probe	Normal	1r2g	1r1g	2r1g	3r3g	1r1g12f	1r1g1f
5q	95%	1%	1%				
7q	95%	1%	2%	2%			
8	95%				1%		
20q	95%	1%	1%	1%			
BCR;ABL1	94%					1%	1%



# Scorpion for MicroFISH

## Produces Paper and Electronic Score Sheets

Acute Myeloid Leukemia (AML)

Patient: Alexander Stevenson

ID: 123456789

<p>ETO/AML1</p> <p>Lot: 1234567890</p> <p>Exp. Date: ---</p>  <p>2 Probes</p>	2R2G - Normal	1R1G2F				
	Normal/Abnormal nuc ish 8q22(RUNX1T1x_),21q22(RUNX1x_),(RUNX1T1 con RUNX1x_)					
<p>PML/RARA</p> <p>Lot: 1234567890</p> <p>Exp. Date: ---</p> 	2R2G - Normal	1R1G2F				
	Normal/Abnormal nuc ish 15q24.1(PMLx_),17q21(RARAx_),(PML con RARA x_) [ ]					

(Image of partial score sheet)

# MicroFISH® Assay System

## Summary

- ❖ The MicroFISH System is a clinically proven, simple-to-use technology in continuous clinical use at Genetics Associates on over 20,000 patient samples
- ❖ Probe hybridizations performed in reduced and controlled humidity dramatically boosts signal intensities and reduced resets by 50%.
- ❖ The Scorpion has been clinically validated for automating cell dropping and probe dispensing and generates patient score sheets for manual or electronic record keeping



# Special Thanks

## Art Robbins Instruments

- David Wright

## Genetics Associates, Inc.

- Mingya Liu
- Cynthia Brooks
- Carrie Johnson
- FISH staff



**SciGene Booth 925**

**See a demonstration  
of the MicroFISH System  
and Scorpion Robot**

**SciGene**

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**[www.scigene.com](http://www.scigene.com)**

# Scorpion for MicroFISH

## Typical Results

